**THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF RHODE ISLAND**

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| **IN RE LOESTRIN ANTITRUST LITIGATION**<br><br>**THIS DOCUMENT RELATES TO:**<br>**END PAYOR PLAINTIFF ACTIONS** | **MDL NO. 2472**<br>**JURY TRIAL DEMAND** |

# END-PAYOR PLAINTIFFS' SECOND AMENDED CONSOLIDATED CLASS ACTION COMPLAINT

Third Party Payor ("TPP") Plaintiffs City of Providence, A.F.of L. - A.C.G. Building Trades Welfare Plan, Allied Services Division Welfare Fund, Electrical Workers 242 and 294 Health & Welfare Fund, Fraternal Order of Police, Fort Lauderdale Lodge 31, Insurance Trust Fund, Laborers International Union of North America, Local 35 Health Care Fund, Painters District Council No. 30 Health & Welfare Fund, Teamsters Local 237 Welfare Benefits Fund, United Food and Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund ("TPP Plaintiffs"), and Consumer Plaintiffs Denise Loy, Melissa Chrestmas and Mary Alexander ("Consumers" and collectively with TPP Plaintiffs, "End-Payor Plaintiffs" or "EPPs") on behalf of themselves and all others similarly situated, file this Consolidated Amended Class Action Complaint against the defendants Allergan plc f/k/a Actavis plc f/k/a Actavis Limited f/k/a Warner Chilcott (see description of Warner Chilcott entities in Parties section below) and Warner Chilcott Limited (collectively, "Warner Chilcott"), Allergan plc f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. (collectively, "Watson"), and Lupin Ltd., and Lupin Pharmaceuticals Inc. (collectively

"Lupin") (Watson and Lupin are collectively referred to as "Generic Defendants," and Warner Chilcott and the Generic Defendants are collectively referred to as the "Defendants"), based upon personal knowledge, the investigation of counsel, and upon information and belief allege as follows:

## I. NATURE OF THE ACTION

1. This civil antitrust action seeks damages arising out of Warner Chilcott's unlawful scheme to impair competition with respect to oral contraceptives with 24 active tablets containing 1 mg norethindrone acetate and 20 mcg ethinyl estradiol and four inactive iron tablets (the "Loestrin 24 drugs" or the "Loestrin 24 market"). Warner Chilcott's scheme, in important parts of which Watson and Lupin colluded, included:

- wrongfully listing a fraudulently obtained patent in the Orange Book;
- asserting the fraudulently obtained patent in sham lawsuits against generic Loestrin 24 manufacturers;
- paying competitor Watson to delay marketing its generic Loestrin 24;
- conspiring with Watson to deter other generic manufacturers from marketing generic Loestrin 24 before Watson entered the market;
- paying competitor Lupin to delay marketing its generic Loestrin 24;
- switching the market from Loestrin 24 to Minastrin 24—a nearly identical product with no benefits or improvements—during that purchased delay; and
- withdrawing Loestrin 24 from the market in order to coerce doctors and patients to switch to Minastrin 24.

Defendants' scheme and unlawful agreements injured EPPs by forcing them to pay supracompetitive prices for Loestrin 24 drugs.

2. *The Wrongful Orange Book Listing.* As part of its NDA for Loestrin 24, Warner Chilcott submitted to the Food and Drug Administration ("FDA") for listing in the Orange Book

U.S. Patent No. 5,552,394 (the "'394 patent"). Warner Chilcott did so despite knowing that it could not reasonably assert the '394 patent against generic manufacturers because it knew that the patent was unenforceable and invalid for obviousness. The drugs claimed in the patent have been used for decades to prevent pregnancy and the only "invention" claimed by the patent was the obvious use of those drugs in a regimen of 24 days instead of 21. But Warner Chilcott did not care about succeeding on the merits of its patent lawsuit. Merely by listing the patent in the Orange Book, Warner Chilcott erected barriers to entry that could delay the onset of generic competition.

3. *The Sham Litigation*. When generic manufacturer Watson sought FDA approval to market generic Loestrin 24, Warner Chilcott prosecuted sham litigation against Watson for infringement of the fraudulently obtained '394 patent. Warner Chilcott never expected to exclude Watson based on the strength of the '394 patent. Warner Chilcott knew that the patent was unenforceable and invalid. Warner Chilcott then later filed additional sham patent litigation against generic manufacturers Lupin and Mylan.

4. *The Exclusion Payments.* Warner Chilcott knew that once it lost its patent lawsuit against Watson its Loestrin 24 product would fall of the "patent cliff"—Watson's generic product would quickly take 85% or more of the unit sales. This competition would save hundreds of millions of dollars for Plaintiffs and other purchasers of Loestrin 24. In order to forestall this competition and consequent loss of sales, and to deprive purchasers of the benefits of that competition, Warner Chilcott paid Watson to delay marketing its generic Loestrin 24. Under the guise of settling the patent lawsuit, Watson agreed to keep its generic Loestrin 24 off the market until January 2013, and in exchange Warner Chilcott agreed to pay Watson at least [redacted]. These payments included:

a. A promise not to market a competing authorized generic ("AG") version of Loestrin 24 during the first 180 days that Watson's generic Loestrin 24 was on the market (worth at least $41.34 million to Watson);

b. A grant to Watson of rights to another Warner Chilcott product, Generess Fe, at below market rates (worth more than [redacted] to Watson).

c. Above-market-rate payments to Watson to help market another Warner-Chilcott product, Femring (worth at least [redacted] to Watson);

d. A promise not to grant a license to any other generic to enter the market until at least six months after Warner Chilcott had entered;

e. A promise that, if any other generic manufacturer entered the market before Watson's agreed entry date of January 2014, Watson's entry date would be accelerated accordingly;

5. To shore up its market allocation agreement with Watson, Warner Chilcott entered into a similar agreement with the second potential generic competitor, Lupin. Warner Chilcott again agreed to share some of the monopoly profits with its potential competitor. Lupin agreed to withdraw its challenge to the '394 patent and delay entry until July 22, 2014—six months after Watson and at patent expiration. In exchange, Warner Chilcott agreed to pay Lupin at least [redacted]. These payments included:

a. A grant to Lupin of rights to another Warner Chilcott product, Femcon Fe, at below-market rates (worth at least [redacted] to Lupin).

b. A grant to Lupin of contingent rights to another Warner Chilcott product, Asacol (400mg), at below market rates (worth at least [redacted] to Lupin).

c. $4 million in cash.

6. *The Exclusionary Product Hop.* But even the unlawfully purchased late entry of generic Loestrin 24 in 2014 was a chimera. By the time the delayed entry dates finally arrived, Warner Chilcott had implemented yet another aspect of its anticompetitive scheme. Before manufacturers of generic Loestrin 24 could begin marketing their products, Warner Chilcott reformulated Loestrin 24 into another product, Minastrin 24, with the purpose and effect of

preventing generic Loestrin 24 from being substitutable for the "new" product at the pharmacy counter.

7. The modifications that Warner Chilcott made to Loestrin 24 to render generic Loestrin 24 non-substitutable had no safety, efficacy, or other benefit of any kind for patients. Minastrin 24 is Loestrin 24 with one tweak: Warner Chilcott added spearmint and a sweetener to the inactive "reminder" pills (only). Warner Chilcott did not do anything to make the *active* Loestrin pills chewable; it did not add sweeteners or flavors to them. Warner Chilcott simply tinkered with the "reminder" pills and changed the label to say that women could chew the pills. (After it had obtained a three-year marketing exclusivity based on the new chewable form, Warner Chilcott amended the label to say that women could, if they wanted, swallow the pills instead.) Warner Chilcott's sole motive in making this modification to the product was to impair generic competition.

8. Once the FDA approved Minastrin 24, Warner Chilcott employed its army of sales force detailers to cannibalize the Loestrin 24 prescriptions, i.e., to aggressively switch them to the new product. Thus, by the time generic versions of Loestrin 24 finally entered the market in 2014, they made few sales because Warner Chilcott had switched the prescription base to Minastrin 24.

9. On October 1, 2013, Actavis acquired Warner Chilcott. In performing due diligence for that acquisition, Actavis knew that Loestrin 24 and another financially important Warner Chilcott drug, Asacol (400mg), would soon be pushed over the patent cliff if Warner Chilcott had done nothing to impair generic competition. Actavis nevertheless pursued the acquisition, assuring its shareholders and potential investors that Warner Chilcott had embarked on a multifaceted scheme that would successfully protect these drugs from generic competition.

For example, Sigurdur Oli Olafsson, Actavis' President of Global Generics, told investors in May 2012 that Actavis was "very impressed" with Warner Chilcott's anticompetitive scheme, which he euphemistically referred to as "the ever-greening line extension strategy."

10. Actavis was right. Warner Chilcott's scheme to impair generic competition has been, to date, very successful. But the scheme and its various parts flagrantly violate the Sherman Antitrust Act. Warner Chilcott thus lined its and its shareholders' pockets with money stolen from purchasers of Loestrin 24 and Minastrin 24. This lawsuit seeks recovery of those stolen funds on behalf of those purchasers.

11. *End-Payor Plaintiffs' Injuries*. But for the anticompetitive scheme and agreements, a generic version of Loestrin 24 would have been available to Plaintiffs and members of the Class in the United States as early as September 2009, when the FDA granted final approval to Watson's generic Loestrin 24. Other generic versions of Loestrin 24, including an authorized generic version marketed directly or indirectly by Warner Chilcott, would have also entered, driving the generic prices to down near marginal cost. Plaintiffs and the members of the Class would have purchased those generic products. Moreover, absent the anticompetitive scheme and agreements, Warner Chilcott would not have been able to substantially reduce the number of Loestrin 24 prescriptions available for generic substitution.

12. Defendants' unlawful scheme and agreements were designed to and did in fact: (a) delay the entry of less expensive generic Loestrin 24 drugs in the United States; (b) fix, raise, maintain or stabilize the price of Loestrin 24 drugs; and (c) allocate 100% of the United States market for Loestrin 24 drugs to Warner Chilcott.

13. Plaintiffs bring this action as a class action on behalf of all consumers and third-party payors (collectively "End-Payor Class") in the United States of America and Puerto Rico

who indirectly purchased, paid or provided reimbursement for branded and/or generic Loestrin 24 drugs, other than for re-sale, since September 2009.

14. Plaintiffs also assert claims for compensatory and/or treble damages and equitable relief for continuing violations of state antitrust and/or consumer protection laws, and for unjust enrichment and disgorgement under common law.

## II. PARTIES

### A. Plaintiffs

15. City of Providence, Rhode Island ("Providence") is a municipal corporation with a principal address of 25 Dorrance Street, Providence, Rhode Island. Providence is a self-insured health and welfare benefit plan, and purchases, pays and/or provides reimbursement to its employees for some or all of the purchase price of prescription drugs, including Loestrin 24 and/or Minastrin 24. Providence indirectly purchased, paid or provided reimbursement for Loestrin 24 and/or Minastrin 24 in, inter alia, Connecticut, the District of Columbia, Florida, Illinois, Maryland, Massachusetts, Missouri, New York, New Jersey, Ohio, Pennsylvania, Rhode Island, South Carolina and Texas, other than for resale and (and will purchase the generic version other than for re-sale once it becomes available). Providence paid more for Loestrin 24 and/or Minastrin 24 than it would have absent Defendants' unlawful anticompetitive conduct and was injured as a result thereof. Absent the unlawful conduct alleged herein, Plaintiff would have purchased less expensive generic alternatives rather than branded Loestrin 24 and/or Minastrin 24.

16. A.F. of L. - A.C.G. Building Trades Welfare Plan, ("the A.F.L. Plan") is a self-insured health and welfare benefit plan with its principal place of business in Mobile, Alabama. The A.F.L. Plan purchases, pays and/or provides reimbursement to its members for some or all of the purchase price of prescription drugs including Loestrin 24 and/or Minastrin 24. The A.F.L.

Plan represents participants who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of Loestrin 24 and/or Minastrin 24 in, inter alia, Alabama, Mississippi, and Tennessee, other than for resale (and will purchase the generic version other than for re-sale once it becomes available). The A.F.L. Plan paid more for Loestrin 24 and/or Minastrin 24 than it would have for Loestrin 24 and/or Minastrin 24 absent Defendants' unlawful anticompetitive conduct and was injured as a result thereof. Absent the unlawful conduct alleged herein, Plaintiff would have purchased less expensive generic alternatives rather than branded Loestrin 24 and/or Minastrin 24.

17. Allied Services Division Welfare Fund ("ASD"), is a health and welfare benefits fund with its principal place of business at 53 West Seegers Road, Arlington Heights, Illinois 60005, and is involved in the business of providing health and pension benefits, among others, to covered lives. Plaintiff has indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Loestrin 24 and/or Minastrin 24, other than for re-sale (and will purchase the generic version other than for resale once it becomes available), at supracompetitive prices in California, Illinois, Kansas, and Ohio during the Class Period. ASD paid more for Loestrin 24 and/or Minastrin 24 than it would have absent Defendants' unlawful anticompetitive conduct and was injured as a result thereof. Absent the unlawful conduct alleged herein, Plaintiff would have purchased less expensive generic alternatives rather than branded Loestrin 24 and/or Minastrin 24.

18. Electrical Workers 242 and 294 Health & Welfare Fund ("EW 242/294") is an employee welfare benefit plan. EW 242/294's headquarters and office responsible for covering medical benefits, including benefits for prescription drugs, is located in Duluth, Minnesota. Plaintiff has indirectly purchased, paid or provided reimbursement for some or all of the

purchase price for Loestrin 24 and/or Minastrin 24, other than for resale (and will purchase the generic version other than for resale once it becomes available), in Minnesota and Virginia at supracompetitive prices during the Class Period, and has thereby been injured. EW 242/294 paid more for Loestrin 24 Fe than it would have absent Defendants' unlawful anticompetitive conduct and was injured as a result thereof. Absent the unlawful conduct alleged herein, Plaintiff would have purchased less expensive generic alternatives rather than branded Loestrin 24 and/or Minastrin 24.

19. Fraternal Order of Police, Fort Lauderdale Lodge 31, Insurance Trust Fund ("FOP") is a health and benefit fund operated for the benefit of present and retired workers of the union and their families. The Fund was established pursuant to a duly executed Trust Agreement for the purpose of providing health benefits, including prescription benefits, to its defined beneficiaries. The Fund maintains its principal place of business in Fort Lauderdale, Florida. The Fund indirectly purchased, paid and/or provided reimbursement for Loestrin 24 and/or Minastrin 24 in, inter alia, Florida, Michigan, New Jersey, and Nevada other than for resale (and will purchase the generic version other than for re-sale once it becomes available). FOP paid more for Loestrin 24 and/or Minastrin than it would have absent Defendants' unlawful anticompetitive conduct and was injured as a result thereof. Absent the unlawful conduct alleged herein, Plaintiff would have purchased less expensive generic alternatives rather than branded Loestrin 24 Fe.

20. Laborers International Union of North America, Local 35 Health Care Fund ("Local 35") is a health and welfare benefit fund and is involved in the business of providing health and pension benefits, among others, to covered lives. Plaintiff has indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Loestrin 24 and/or

Minastrin, other than for resale (and will purchase the generic version other than for resale once it becomes available), at supracompetitive prices in New York and South Carolina during the Class Period. Local 35 paid more for Loestrin 24 and/or Minastrin than it would have absent Defendants' unlawful anticompetitive conduct and was injured as a result thereof. Absent the unlawful conduct alleged herein, Plaintiff would have purchased less expensive generic alternatives rather than branded Loestrin 24 and/or Minastrin 24.

21. Painters District Council No. 30 Health & Welfare Fund ("Painters Fund") is located in Aurora, Illinois. Painters Fund is an "employee welfare benefit plan" and an "employee benefit plan" within the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. §§1002(1), 1002(3) and 1003(a). As such, Painters Fund is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. §1132(d). Painters Fund is a not-for-profit trust, sponsored by and administered by a Board of Trustees, established and maintained to provide comprehensive health coverage for its participants and beneficiaries. Painters Fund is an indirect purchaser of Loestrin 24 and Minastrin (and will purchase its generic equivalent once it becomes available) during the Class Period and was injured by Defendants' unlawful conduct. Painters Fund sustained injury when it purchased, paid and/or provided reimbursement for purchases of Loestrin 24 and Minastrin 24 in Florida, Illinois, Nevada, and South Dakota Painters Fund paid more for Loestrin 24 and Minastrin 24 than it would have absent Defendants' unlawful anticompetitive conduct and was injured as a result thereof. Absent the unlawful conduct alleged herein, Plaintiff would have purchased less expensive generic alternatives rather than branded Loestrin 24 and/or Minastrin 24.

22. Teamsters Local 237 Welfare Benefits Fund ("Teamsters Local 237 Fund") is a trust fund administered pursuant to the requirements of the Taft-Hartley Act, 29 U.S.C. § 186, by

an equal number of trustees appointed by labor representatives and union representatives. Plaintiff is an "employee welfare benefit plan" and "employee benefit plan" maintained pursuant to § 302(c)(5) of the Labor Management Relations Act ("LMRA"), 29 U.S.C. § 186(c)(5), and as defined by § 1002(1) and (3) of the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C § § 1001, et seq. As such, Plaintiff is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. § 1132(d). Plaintiff's office is located in New York. During the relevant period, Plaintiff indirectly purchased, paid and/or provided reimbursement for its members' Loestrin 24 and Minastrin 24 purchases in, inter alia, Connecticut, New York and New Jersey, other than for resale (and will purchase the generic version other than for re-sale once it becomes available). Teamsters Local 237 Fund paid more for Loestrin 24 and Minastrin 24 than it would have absent Defendants' unlawful anticompetitive conduct and was injured as a result thereof. Absent the unlawful conduct alleged herein, Plaintiff would have purchased less expensive generic alternatives rather than branded Loestrin 24 and Minastrin24.

23. United Food and Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund ("UFCW") maintains its principal place of business at 3031-A Walton Road, Plymouth Meeting, Pennsylvania 19462. Plaintiffs have indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Loestrin 24 and Minastrin 24, other than for re-sale (and will purchase the generic version other than for re-sale once it becomes available), in Florida, New Jersey, Delaware, and Pennsylvania at supra-competitive prices during the Class Period, and has thereby been injured. UFCW paid more for Loestrin 24 and Minastrin 24 than it would have absent Defendants' unlawful anticompetitive conduct and was injured as a result thereof. Absent the unlawful conduct alleged herein, Plaintiff would have purchased less expensive generic alternatives rather than branded Loestrin 24 Fe.

24. Denise Loy is an adult, individual consumer, residing in Indian Harbor Beach, Florida. Plaintiff Loy has indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of Loestrin 24 and/or Minastrin 24, other than for resale (and will purchase the generic version other than for resale once it becomes available), at supracompetitive prices during the Class Period, and has thereby been injured. Absent the unlawful conduct alleged herein, Plaintiff would have purchased less expensive generic alternatives rather than branded Loestrin 24 and/or Minastrin 24.

25. Melissa Chrestmas is an adult, individual consumer, residing in Goodlettsville, Tennessee. Plaintiff Chrestman has purchased or paid for some or all of the purchase price of Loestrin 24 and/or Minastrin 24 other than for resale (and will purchase the generic version other than for resale once it becomes available), at supracompetitive prices during the Class Period, and has been injured. Absent the unlawful conduct alleged herein, Plaintiff would have purchased less expensive generic alternatives rather than branded Loestrin 24 and/or Minastrin 24.

26. Mary Alexander is an adult, individual consumer, residing in Granite Quarry, North Carolina. Plaintiff Alexander has purchased or paid for some or all of the purchase price of Loestrin 24 and/or Minastrin 24 other than for resale (and will purchase the generic version other than for resale once it becomes available), at supracompetitive prices during the Class Period, and has been injured. Absent the unlawful conduct alleged herein, Plaintiff would have purchased less expensive generic alternatives rather than branded Loestrin 24 and/or Minastrin 24.

**B. Defendants**

27. The defendants' names, and the corporate relationships between and among them, have changed over time. Currently, the Warner Chilcott and Watson entities are part of the multinational corporation, Allergan plc.

28. Defendant Warner Chilcott Limited is incorporated under the laws of Bermuda with its principal place of business at Cannon's Court 22, Victoria Street, Hamilton HM 12, Bermuda.

29. Defendant Warner Chilcott (US), LLC is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 100 Enterprise Drive, Rockaway, New Jersey 07866.

30. Defendant Warner Chilcott Sales (US), LLC is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 100 Enterprise Drive, Rockaway, New Jersey 07866.

31. Defendant Warner Chilcott Company, LLC is a limited liability company organized and existing under the laws of Puerto Rico, having its principal place of business at Road 195, Km. 1.1, Union Street, Fajardo, Puerto Rico. It maintains a place of business at 100 Enterprise Drive, Rockaway, New Jersey 07866.

32. Defendant Warner Chilcott plc is a public limited company incorporated under the laws of Ireland, with its principal place of business at 1 Grand Canal Square, Docklands, Dublin 2, Ireland. It maintains a place of business at 100 Enterprise Drive, Rockaway, New Jersey 07866.

33. The foregoing defendants are collectively referred to herein as "Warner Chilcott."

34. Defendant Watson Laboratories, Inc. is a company organized and existing under the laws of Nevada, having its principal place of business at 311 Bonnie Circle, Corona,

California 92880. Watson Laboratories, Inc. is a wholly-owned subsidiary of Watson Pharmaceuticals, Inc., which became Actavis, Inc.

35. Defendant Actavis, Inc. is a company organized and existing under the laws of Nevada, having its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

36. Actavis, Inc., Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. are collectively referred to herein as "Watson." Watson is engaged in the worldwide marketing, production and distribution of generic pharmaceutical products, including in this judicial district.

37. Effective on or about January 24, 2013, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. and continued operating under the name Actavis, Inc.

38. Defendant Actavis, Inc. acquired Warner Chilcott plc on October 1, 2013 and continued to operate under the name Actavis plc.

39. In March 2015, Actavis plc acquired Defendant Allergan plc. On June 15, 2015, Actavis plc announced that it would change its name to Allergan plc ("Allergan"). Allergan markets branded and generic pharmaceuticals throughout the United States and has commercial operations in the United States and approximately 100 countries around the world. Defendant Allergan plc is a public limited company incorporated under the laws of Ireland, with its principal place of business at 1 Grand Canal Square, Docklands, Dublin 2, Ireland. Allergan maintains a place of business within the United States at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, 07054.

40. Defendant Lupin Ltd. is a company organized and existing under the laws of India, having its principal place of business at B/4 Laxami Towers, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400051, India.

41. Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Virginia, having its principal place of business at Harbor Place Tower, 111 South Calvert Street, 21st floor, Baltimore, Maryland 21202. Lupin Pharmaceuticals is a wholly-owned subsidiary of Defendant Lupin Ltd.

42. All of the defendants' actions described in this complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by the defendants' various officers, agents, employees, or other representatives while actively engaged in the management of the defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the defendants' actual, apparent, and/or ostensible authority.

## III. JURISDICTION AND VENUE

43. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which the aggregate amount in controversy exceeds $5,000,000 and at least one member of the putative class is a citizen of a state different from that of one of the Defendants.

44. This Court also has jurisdiction over this matter pursuant to 15 U.S.C. § 26 and 28 U.S.C. §§ 1331 and 1337 in that Plaintiffs bring claims under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy Defendants' violations of Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S. C. § 1 and 2. The Court has supplemental jurisdiction over Plaintiffs' pendent state law claims pursuant to 28 U.S.C. § 1367.

45. Venue is appropriate within this district under Section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. §1391(b) and (c), because Defendants transact business within this district and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district.

## IV. INDUSTRY BACKGROUND

### A. Characteristics of the Prescription Pharmaceutical Marketplace

46. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that brand manufacturers can exploit in order to obtain or maintain market power in the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the price of the product plays an appropriate role in the person's choice of products and, consequently, the manufacturers have an appropriate incentive to lower the prices of their products.

47. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Loestrin 24, to patients without a prescription written by a doctor. The prohibition on dispensing certain products without a prescription introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

48. Warner Chilcott and other brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

49. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand—the extent to which unit sales go down when price goes up. This reduced price elasticity in turn gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise price substantially above marginal cost is what economists and antitrust courts refer to as market power. The result of the market imperfections and marketing practices described above is to allow brand manufacturers to gain and maintain market power with respect to many branded prescription pharmaceuticals.

### B. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs

50. The relevant drug-regulatory framework is established by the Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 ("Hatch-Waxman Amendments"). Under FDCA, branded drug manufacturers that wish to sell a new drug product must obtain approval from the Food and Drug Administration ("FDA") by filing a New Drug Application ("NDA"). 21 U.S.C. § 355(b). The NDA must include, among other things, a statement of the drug's components, active ingredients, scientific data showing that the drug is safe and effective, patent information, and proposed labeling describing the methods by which a drug may be used and administered. 21 U.S.C. §§ 355(a), (b).

51. Upon FDA approval of the NDA, the FDA lists in the Orange Book any patents that the manufacturer asserts could reasonably be enforced against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. If a relevant patent issues after FDA approval, the manufacturer may submit the patent for listing in the Orange Book within thirty days of its issuance. 21 U.S.C. §§ 355(b)(1) & (c)(2).

52. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, because it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

**1. The Hatch-Waxman Amendments**

53. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to their brand-name counterpart an "AB" rating.

54. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

55. Congress enacted the Hatch-Waxman Amendments to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

56. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic high profit margins for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for brand and generic drugs totaled $21.6 billion; by 2013, total prescription drug revenue had climbed to more than $329.2 billion, with generic drugs accounting for 86% of prescriptions. Generics are now dispensed 95% of the time when a generic form is available.

**2. ANDA Paragraph IV Certifications**

57. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, 21 U.S.C. § 355(j)(2)(A)(vii), a generic manufacturer's ANDA must contain one of four certifications:

> (I) that no patent for the brand drug has been filed with the FDA (a "paragraph I certification");
>
> (II) that the patent for the brand drug has expired (a "paragraph II certification");
>
> (III) that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "paragraph III certification"); or

(IV) that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "paragraph IV certification").

58. If a generic manufacturer files a paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the paragraph IV certification ("paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product. The FDA grants tentative approval when the product meets all applicable regulatory requirements, but final approval is prohibited by a branded drug manufacturer's exclusivity.

**3. The First Filer's 180-day Exclusivity Period**

59. Generics may be classified as (i) first filer generics, (ii) later generic filers, and (iii) authorized generics.

60. To encourage manufacturers to seek approval of generic versions of branded drugs, the Hatch-Waxman Amendments grant the first generic manufacturer that submits an ANDA containing a paragraph IV (the "first filer") a 180-day exclusivity period to market the generic version of the drug, during which the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand-name drug. 21 U.S.C. § 355(j)(5)(B)(iv) and 21 U.S.C. § 355(j)(5)(D). That is, when a first filer files a substantially complete ANDA with the FDA and certifies that the unexpired patents listed in the Orange Book as covering the branded product are either invalid or not infringed by the generic's product, the FDA cannot approve any successive generic filer's ANDA that contains a paragraph IV certification to the

same patent(s) until either 180 days after the first filer enters the market or the first filer's exclusivity is forfeited, whichever is sooner.

61. The 180-day window is referred to as the first filer's six-month or 180-day "exclusivity," though it is a bit of a misnomer, because a brand drug manufacturer (such as Warner Chilcott) can launch an authorized generic ("AG") version of its own brand drug, under its own NDA at any time. Brand companies frequently do so in response to generic entry in order to recoup some of the sales they would otherwise lose.

62. The Supreme Court has recognized that "this 180-day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars'" to the first filer.

63. A first filer that informs the FDA that it intends to wait until all Orange Book listed patents expire before marketing its generic does not get a 180-day exclusivity period. Congress created this 180-day period to incentivize generic manufacturers to challenge weak or invalid patents, or to invent around such patents by creating non-infringing generics.

64. Amendments to Hatch Waxman provide that a first-filer forfeits its 180-day exclusivity by, for example, failing to obtain tentative approval within 30 months of filing.

**C. The Competitive Effects of AB-rated Generic Competition.**

65. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective as their brand name counterparts. The only material difference between generic drugs and their corresponding brand name versions is their price. Because generic versions of a corresponding branded drug product are commodities that cannot be differentiated, the primary basis for generic competition is price. Typically, generics are at least 25% less expensive than their brand name counterparts when there is a single generic competitor, and this discount typically increases to 50% to 80% (or more) when

there are multiple generic competitors on the market for a given brand. Consequently, the launch of a generic drug usually results in significant cost savings for all drug purchasers.

66. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute AB-rated generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise). Substitution laws and other institutional features of pharmaceutical distribution and use create the economic dynamic that the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing. Once a generic equivalent hits the market, the generic quickly captures sales of the corresponding branded drug, often capturing 80% or more of the market within the first six months. In a recent study, the Federal Trade Commission ("FTC") found that on average, within a year of generic entry, generics had captured 90% of corresponding brand drug sales and (with multiple generics on the market) prices had dropped 85%.[1] As a result, competition from generic drugs is viewed by brand name drug companies, such as Warner Chilcott, as a grave threat to their bottom lines.

67. Generic competition enables all members of the proposed class to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the brand drug at a reduced price.

68. Until a generic version of the brand drug enters the market, however, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices. Brand

[1] See FTC Staff Study, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (January 2010), http://www ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

[2] FTC, *Authorized Generic Drugs: Short-Terms Effects and Long-Term Impact*, at ii-iii, vi, 34 (Aug. 2011), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf ("FTC 2011 AG Study"); FTC Pay-for-Delay Study at 1.

[3] *See*, *e.g.*, Patricia Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, J.L.& Econ. (Oct. 2000); Tracy Regan, *Generic Entry and Price Competition in the Prescription Drug Market – 18*

manufacturers, such as Warner Chilcott, are well aware of generics' rapid erosion of their brand sales. Brand manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to any means possible—including illegal means.

**1. The fist AB-rated generic is priced below the brand.**

69. Experience and economic research show that the first generic manufacturer to market its product prices it below the prices of its brand counterpart.[2] Every state either requires or permits that a prescription written for the brand drug be filled with an AB-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the brand form of the drug. At the same time, there is a reduction in average price paid for a prescription for the drug at issue (brand and AB-rated generic combined).

70. During the 180-day exclusivity period, the first filer is the only ANDA-approved generic manufacturer on the market (as noted above, the brand's AG can be, and often is, on the market during the 180-day exclusivity period). In the absence of competition from other generics, during the 180-day exclusivity period a first-filer generic manufacturer generally makes about 80% of all of the profits that it will ever make on the product.

**2. Later Generics Drive Prices Down Further.**

71. Once multiple generic competitors enter the market, the competitive process accelerates and the generic sellers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.[3]

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[2] FTC, *Authorized Generic Drugs: Short-Terms Effects and Long-Term Impact*, at ii-iii, vi, 34 (Aug. 2011), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf ("FTC 2011 AG Study"); FTC Pay-for-Delay Study at 1.

[3] *See*, *e.g.*, Patricia Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, J.L.& Econ. (Oct. 2000); Tracy Regan, *Generic Entry and Price Competition in the Prescription Drug Market – 18 Years after the Waxman-Hatch Act*, (Univ. of Miami, Dep't of Econ., Working Paper, 2004); R. Frank, *The Ongoing Regulation of Generic Drugs*, New Eng. J. Med., v. 357, n. 20 (Nov. 2007), pp. 1993-1996 ("Frank (2007)").

72. According to the FDA and the FTC, the greatest price reductions are experienced when the number of generic competitors goes from one to two. In that situation, there are two commodities that compete on price. Some typical estimates are that a single generic results in a near term retail price reduction of around 10% as compared to the brand price, but that with two generic entrants the near term retail price reduction is about 50%.

73. In a report by the FTC issued at the request of Congress in 2011, the FTC found that generics captured 80% or more of sales in the first six months. FTC 2011 AG Study at 66-67. In the end, total payments to the brand manufacturer decline to a small fraction of the amounts paid before generic entry. This is so because, "[a]lthough generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics."[4]

**3. Authorized Generics Compete on Price, Like Other Generics.**

74. Nothing prevents a brand manufacturer from selling an AG at any time. An AG is chemically identical to the brand drug, but is sold as a generic product, typically through either the brand manufacturer's subsidiary (if it has one) or through a third-party distributor. An AG is essentially the brand drug but in a different package.

75. One study notes that "pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed 'authorized generics.'"[5]

[4] *See* FDA Website, Generic Drugs: Questions and Answers, http://www fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100 htm.

[5] K.A. Hassett, K. A. and & R. J. Shapiro, "*The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals*,", Sonecon, 3 (May 2007, p. 3.).

76. Brand manufacturers sometimes begin selling AGs before the first-filer generic enters the market, in order to secure multi-year purchase contracts with direct purchasers and load the generic pipeline at the expense of the first-filer generic.

77. Competition from an AG substantially reduces drug prices and the revenues of the first-filer generic (especially during the 180-day exclusivity period when no other ANDA generic can be on the market). A study analyzing three examples of AGs found that "[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand."[6]

78. In a report by the FTC issued at the request of Congress in 2011 the FTC found that AGs capture a significant portion of sales, reducing the first-filer generic's revenues by approximately 50% on average. FTC 2011 AG Study at 139. The first-filer generic makes much less money when it faces competition from an AG because (a) the AG takes a large share of unit sales away from the first filer; and (b) the presence of the AG causes prices, particularly generic prices, to decrease.

### D. Pharmaceutical Manufacturers Game the Regulatory Structure In Order to Impair Competition.

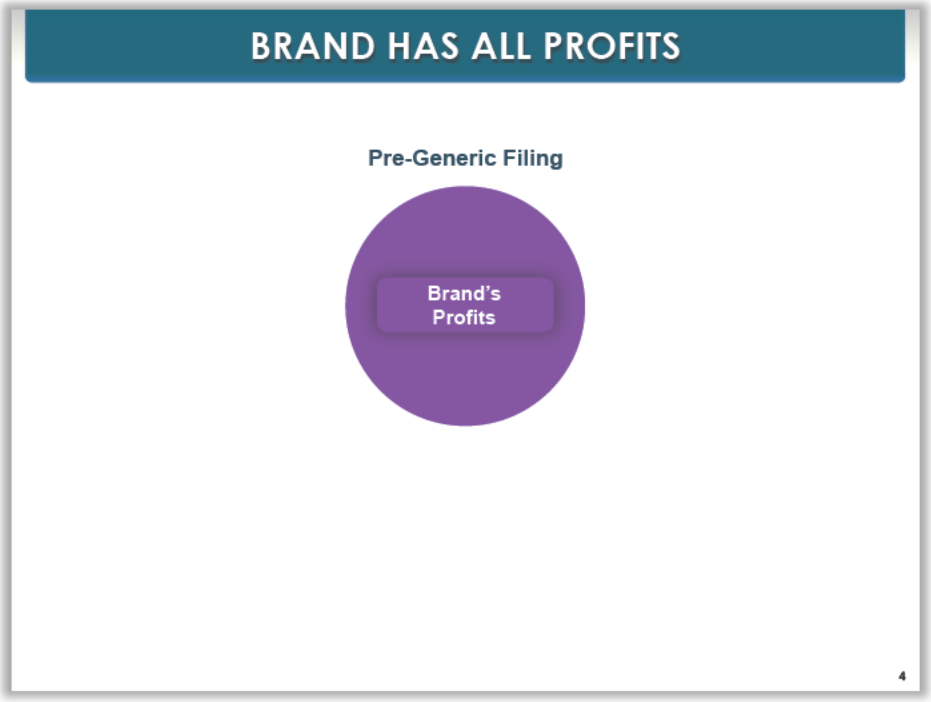
79. When they do not face generic competition, manufacturers of brand drugs can usually sell them far above the marginal cost of production, generating profit margins in excess of 70% while making hundreds of millions of dollars in sales. The ability to make those kinds of profit margins is what economists call market power. When generics enter the market, however, they quickly take 90% or more of the unit sales. And when multiple generics are in the market,

[6] E. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, 26 Health Affairs 796 (2007).

the competition between the generics drives their prices to near only 10% above the marginal cost of production. This competition puts an end to the brand manufacturer's market power and delivers enormous savings to drug purchasers.

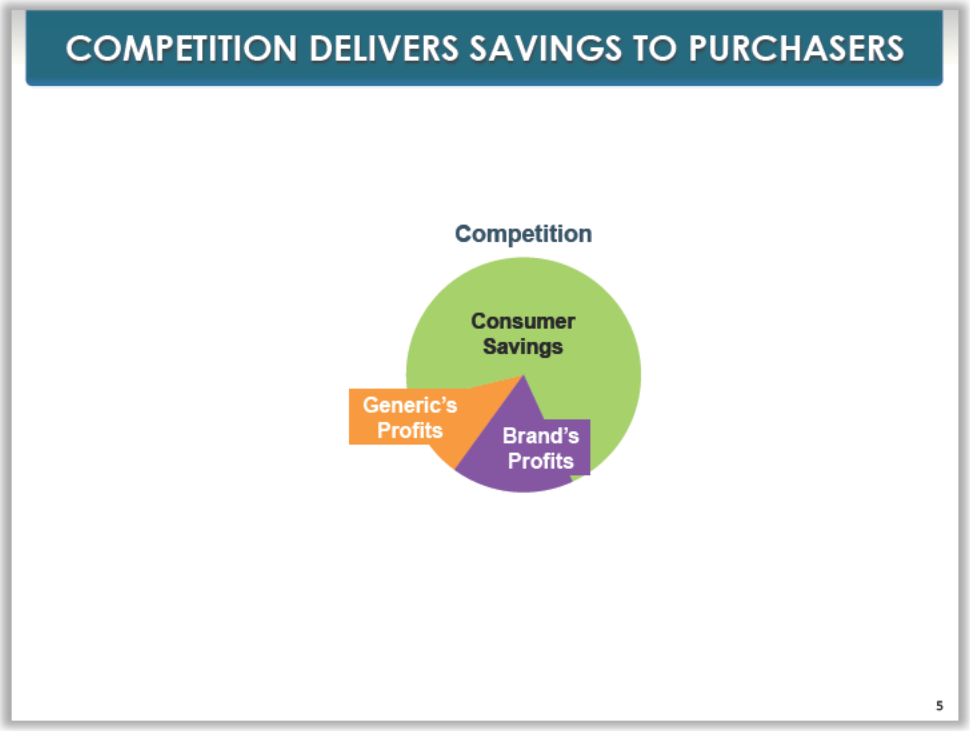
80. The brand and generic manufacturers have a collective interest in preventing this competition from breaking out. If they work together to prevent or delay competition, they can keep the profit margins on all of the unit sales at 70% rather than 10% and split the resulting excess profits among themselves. They can keep the enormous savings that competition would have delivered to drug purchasers. The following series of pie charts demonstrates the manufacturers' collective interest in delaying competition.

81. A brand manufacturer in the marketplace without competition from generics gets all of the profits on all of the unit sales:

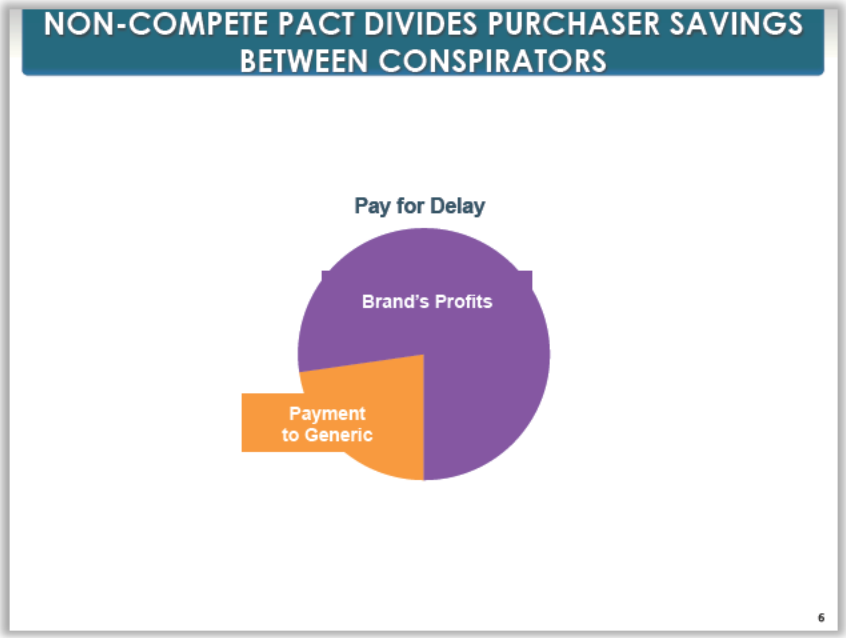



82. When generic entry occurs, the brand manufacturer loses most of the unit sales; the generic manufacturers sell most of the units, but at drastically reduced prices; and

competition delivers enormous savings to consumers. Competition converts what formerly were excess profits into purchaser savings:




83. To avoid this happening, the brand and generic manufacturer can agree not to compete and instead split the purchaser savings between themselves:




84. In order for such an anticompetitive pact to work, the brand and generic manufacturers need a means by which to divide the purchaser savings between themselves. The generic manufacturer will not refrain from competing if it does not share in the ill-gotten gains. Pay-offs from the brand manufacturer are the means by which the brand and generic manufacturers divide between themselves the ill-gotten gains that the delayed competition makes possible. These unlawful pay-off deals are often referred to as "pay-for-delay" agreements or "exclusion payment" agreements.

85. It is often necessary for the brand manufacturer to pay off only the first generic manufacturer that included a paragraph IV Certification in its ANDA, the so-called first-filer. The first-filer's agreement to delay marketing its drug may also prevent other generic manufacturers from marketing theirs. Later ANDA filers have more modest financial expectations because they have no expectation of any form of market exclusivity. By the time

they enter the market there is at least the brand and one other generic on the market (and often a second generic in the form of an AG) and, thus, the drug has already been commoditized.

86. In the absence of an anticompetitive agreement between the brand company and the first filer, the later ANDA filers have procompetitive incentives. They are motivated to expend resources to challenge the brand company's patent(s) (knowing that the first-filer generic is also fighting a patent infringement suit) and to enter the market as early as possible.

87. When an anticompetitive agreement with the first filer is already in place, however, litigation becomes less attractive to later filers. The later generic manufacturers know that the first filer is not leading the charge against the brand's patent(s) (and has sometimes stipulated to the validity or enforceability of the patents as part of an anticompetitive, reverse payment settlement). The later generics have to bear the brunt of the litigation costs themselves, and, upon prevailing in the patent litigation, expect to face competition from at least the first filer generic, and typically an authorized generic as well, despite having expended time and resources litigating the infringement case. The first settlement between a brand and first-filer generic (such as the Exclusion Payment Agreement at issue here) will often provide that, if a later generic filer launches its generic before the delayed date agreed to by the brand and the first filer, the first filer is permitted to launch then as well—greatly reducing the incentive the later filer would otherwise have to continue fighting to enter as soon as possible.

88. Thus, some later generics decide to simply give in to the conspiracy between the brand manufacturer and the first-filer generic and agree to drop their challenges to the brand's patent(s) and stay off the market until after entry by the first filer.

89. Exclusion payment agreements are fundamentally anticompetitive and contrary to the goals of the Hatch-Waxman statutory scheme. In particular, they extend the brand

manufacturer's monopoly by blocking access to more affordable generic drugs, forcing purchasers to buy the expensive brands instead.

### E. No-AG Clauses Provide a Means for Manufacturers to Share the Gains from Conspiring.

90. In the 1990s, the pay-offs from brand manufacturers often took the form of cash payments to the generic competitor. As a result of regulatory scrutiny, congressional investigations, and class action lawsuits, since the 2000s, brand and generic manufacturers have entered into increasingly elaborate agreements in an attempt to hide the pay-offs.

91. One form of pay-off at issue in this case is a no-authorized-generic clause ("no-AG" clause). Pursuant to a no-AG clause, the brand manufacturer agrees not to market an authorized generic version of the brand drug for some period of time after the first-filer enters.

92. As described above, the first filer's ANDA exclusivity does not prohibit the brand manufacturer from marketing its *NDA-based* AG. The Hatch-Waxman amendments' 180-day marketing period is "exclusive" only as against other ANDA-based products, not as against the brand manufacturer's NDA-based AG.

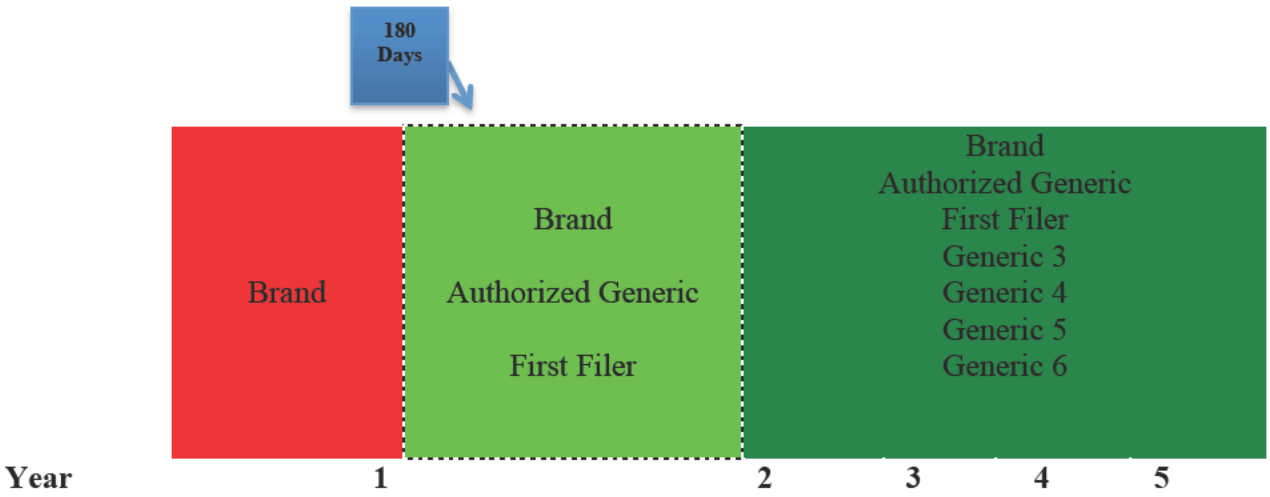
93. Absent a no-AG clause, it almost always makes economic sense for the brand manufacturer to begin marketing an AG as soon as (or weeks or months before) the first generic manufacturer enters the marketplace. As described above, however, competition from an AG has a drastically negative effect on the first-filer generic's revenue. Competition from an AG during typically cuts the first filer's revenues by more than half, as the competing generic takes a substantial volume of the unit sales and drives prices lower—and delivers commensurate savings to drug purchasers.

94. To prevent an AG from causing this substantial loss of revenue and profit, a first-filer generic may be willing to delay its entry into the marketplace in return for the brand

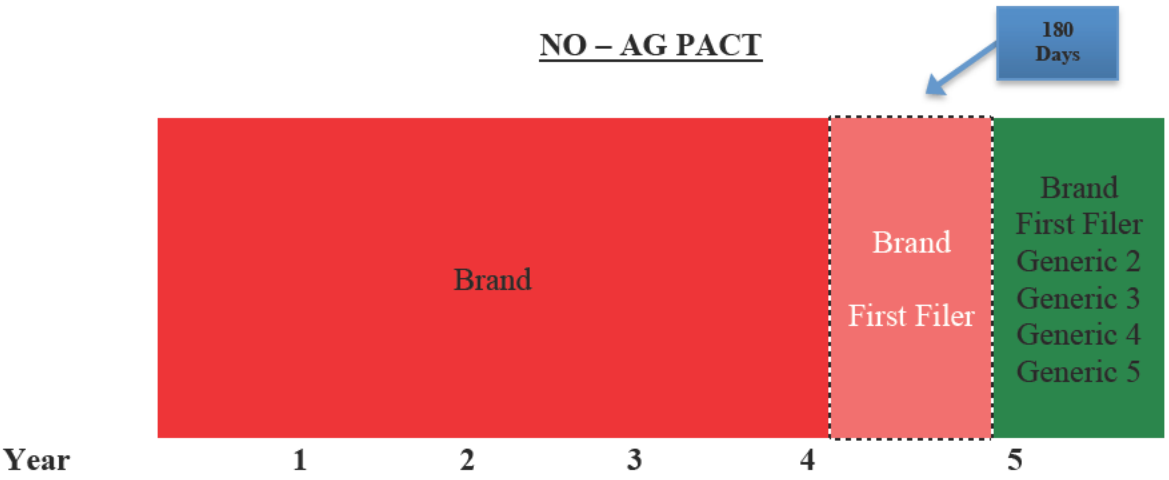
manufacturer's agreement to forgo competing with an AG. The additional monopoly profits that the brand manufacturer gains from the delayed onset of generic competition more than makes up for the profits that it forgoes by not competing with an AG. The brand manufacturer gains from the delayed onset of generic competition. The first filer gains from the absence of generic competition for the first 180 days of marketing. And drug purchasers lose—first by the delay in the onset of generic competition, and then by the absence of AG competition once generic entry finally occurs.

95. The state of competition without unlawful restraints, i.e., without a No-AG clause, is depicted here:

**COMPETITION**




96. The state of competition with a No-AG clause is depicted here:




97. The brand and first filer's reciprocal pledges not to compete harm purchasers thrice over. The pact delays the first filer's entry into the marketplace and thereby extends the time during which the brand is the only product on the market. By delaying the first filer's entry, the pact also delays the time when other generics enter. And the pact prevents the brand from marketing an AG during the 180-day exclusivity period, reducing rivalry during that time from three competitors to two.

98. For the first filer, the difference between selling the only generic and competing against an AG for 180 days can amount to tens or even hundreds of millions of dollars. A no-AG pledge thus has the same economic effect as a pay-off made in cash. As explained by the then-Chairman of the FTC:

> Because the impact of an authorized generic on first-filer revenue is so sizable, the ability to promise not to launch an AG is a huge bargaining chip the brand company can use in settlement negotiations with a first-filer generic. It used to be that a brand might say to a generic, "if you go away for several years, I'll give you $200 million." Now, the brand might say to the generic, "if I launch an AG, you will be penalized $200 million, so why don't you go away for a few years and I won't launch an AG.[7]

[7] *Statement of Chairman Jon Leibowitz on the Release of the Commission's Interim Report on Authorized Generics*, June 2009, http://www.ftc.gov/os/2009/06/P062105authgenstatementLeibowitz.pdf.

99. For a first filer (like Watson) of a branded product that sold hundreds of millions of dollars annually (like Loestrin 24), the difference between selling a generic product without having to compete against an AG and selling in competition with an AG can amount to hundreds of millions of dollars. These economic realities are well known in the pharmaceutical industry. No-AG agreements like the one between Warner Chilcott and Watson thus allow competitors to benefit from an agreement not to compete and deny purchasers the consumer surplus that should flow to them from increased competition.

100. Pay-offs by means of No-AG clauses usually exceed the value that the first-filer could have obtained *even if it had won* the patent infringement litigation. As noted above, during the first six months the first-filer typically makes 80% of all the profits it will ever make on the product. As a reward for winning the patent litigation, the Hatch-Waxman Amendments provide the first-filer a period of 180 days of ANDA Exclusivity. But the Hatch-Waxman Amendments do not prevent the brand manufacturer from marketing an authorized generic during that time, and the brand manufacturer would market an authorized generic if the generic manufacturer entered the market by means of winning the patent case. By settling the patent case in exchange for a No-AG pay-off, the first-filer converts that critical six months into a period of total generic exclusivity, thus doubling its unit sales and making those sales at a vastly higher price.

**F. Manufacturers Use Anticompetitive Acceleration Clauses.**

101. Brand and generic manufacturers can make their Exclusion Payment agreements more effective by including "acceleration" clauses in their settlement agreements. The manufacturers may provide that, in exchange for the No-AG clause, the first-filer will delay entering the market until, say, five years in the future. But the acceleration clause then provides

that if any other generic manufacturer succeeds in entering the market before that date, the first-filer's entry date is accelerated to that earlier date.

102. The acceleration clauses do not accelerate generic entry—they delay it. The purpose and effect of an acceleration clause is to dramatically reduce any other generic manufacturer's incentive to try to enter the market before the first-filer. Absent the acceleration clause, other generic manufacturers would have a possibility (due to the forfeiture provisions discussed above) of entering the market before the first-filer, thereby enjoying a substantial period with the only ANDA-based generic product on the market. By eliminating this possibility, an acceleration clause results in delayed generic entry in at least two ways: (i) the clause directly reduces other generic manufacturers' incentives to file an ANDA or continue litigation in order to gain entry before the first-filer, and (ii) by eliminating the threat to the first-filer's 180-day exclusivity, the clause compensates the first-filer for delaying its entry into the market. In short, the acceleration clause eliminates other generic manufacturers' competitive threat to the first-filer, in return for which the first-filer agrees to later entry than it otherwise would.

103. The Chairman and CEO of Apotex, Inc.—one of the largest generic manufacturers in the world—twice testified to Congress that acceleration clauses, or what he referred to as "poison pill" provisions, represent "the primary anticompetitive aspects of settlements" because they "eliminate any incentive for a subsequent filer to continue to litigate for earlier market entry."[8] The clauses deter others from entering earlier and cause the first-filer to accept a later entry date:

> "[N]o subsequent filer is going to take up the patent fight knowing it will get nothing if it wins. Consumers are the biggest losers

[8] *Protecting Consumer Access to Generic Drugs Act of 2007: Hearing on H.R. 1902 Before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy & Commerce*, 110th Cong., at 65, 67 (2007) (statement of Bernard Sherman, CEO, Apotex, Inc.), *available at* http://www.gpo.gov/fdsys/pkg/CHRG-110hhrg38992/pdf/CHRG-110hhrg38992.pdf.

> under this system. If subsequent filers do not have the incentive to take on the cost of multimillion patent challenges these challenges will not occur. Weak patents that should be knocked out will remain in place, unduly blocking consumer access to generics. The challenges to brand patents by generic companies that Hatch-Waxman was designed to generate will decrease. And settlements that delay consumer access to the generic will, in turn, increase."[9]

104. Most settlement agreements between brand and generic manufacturers provide that the agreement's terms are confidential, except that the brand manufacturer is permitted to advise other generic manufacturers of the existence of the acceleration clause. The purpose and effect of permitting this disclosure is to dissuade other generic manufacturers from trying to enter the market before the delayed entry date to which the first-filer agreed.

### G. Brand Manufacturers Use Anticompetitive Product Hops.

105. Another way that brand manufacturers impair generic competition is by preventing the generic from being AB-rated to the brand drug and thereby impairing generic substitution. The AB-rating requirement for generic drugs is designed to ensure therapeutic equivalence to the reference product. It is concerned only with safety and efficacy and not with effects on competition.

106. FDA regulations permit brand manufacturers to seek FDA approval to modify the dosage form and strength of their existing products. An unscrupulous brand manufacturer that anticipates the onset of generic competition to its drug can modify the dosage form, strength, or some other characteristic of its product from, say, A to $A_1$, for the purpose of preventing the anticipated generic product from being A-B rated to the new brand product. Before the generic

[9] *Protecting Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706 Before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy & Commerce*, 111th Cong., at 218 (2009) (statement of Bernard Sherman, CEO, Apotex, Inc.) (hereinafter "Apotex 2009 Statement"), *available at* http://www.gpo.gov/fdsys/pkg/CHRG-111hhrg67822/pdf/CHRG-111hhrg67822.pdf. Apotex addressed acceleration clauses in the context in which the first-filing generic retained the 180-day exclusivity. But the clauses have the same—or worse—anticompetitive effect where, as here, the first-filer forfeited its exclusivity. In both instances, the acceleration clause all but eliminates the later generic manufacturer's incentive to try to enter before the scheduled date.

manufacturer receives FDA approval for the generic version of A and enters the market, the brand manufacturer can get approval for $A_1$ and cannibalize the sales of A—using its massive sales force to get doctors to switch their prescriptions from A to $A_1$. Thus, before the generic of A enters the market the brand manufacturer will have: (a) ensured that the generic product cannot be A-B rated to, and substitutable for, $A_1$; and (b) switched the prescription base from A to $A_1$. Consequently, when the generic finally gets FDA approval to enter the market, it will garner few or no sales because it is not substitutable for the new brand product to which the prescription base has been switched.

107. The timing of the product hop is critical. It is well known in the pharmaceutical industry that if generic versions of the original brand product enter the market before the branded follow-on product, the latter will make very few sales unless it offers substantial, demonstrable medical benefits to consumers. For example, one brand manufacturer estimated that it would make ten times more sales of its branded follow-on product if it beat generic versions of the original product onto the market. In a detailed inquiry into the pharmaceutical industry, the European Commission concluded that "it is of utmost importance for the originator company to bring the follow-on product on the market before the first product effectively loses exclusivity." European Commission, Final Report, p. 356 (8 July 2009), available at http://www.europa-nu.nl/id/vi6wcj7amsx3/pharmaceutical_sector_inquiry_fianl?start-006-00c=10. Industry analysts in the United States have reached the same conclusion, warning brand manufacturers that it is essential that they switch patients to the new formulation before the generic enters.

108. It is equally well known that, after a product hop, doctors are unlikely to prescribe the original product—in this case, Loestrin 24. Having switched their prescribing habits from the original to the reformulated product—and having switched specific patients' medications from

the original to a reformulated product—most doctors will not switch their prescribing habits or their patients back to the original product after the generic is available. And pharmacists are unable to effect the switch through the efficient mechanism of automatic substitution because the dosage form and/or dosage amount is different. Thus, in most instances, the generic's opportunity to compete for those sales is gone forever.

109. Brand manufactures know that, if they successfully cannibalize the original product's sales before the generics enter the market, generic competition will be very substantially impaired. Automatic substitution at the pharmacy counter is a generic product's most efficient means of competing. Generally, once the brand's patents are no longer effective, *no one*—neither the brand manufacturer nor any generic manufacturers—can effectively market the product on a basis other than price. Costs incurred to encourage a doctor to write a prescription for one's product would be squandered because the pharmacist can fill the prescription with a competitor's A/B-rated product unless the doctor writes "dispense as written" or a similar restriction. And this is a good thing. If a manufacturer could profitably market the product to doctors on a basis other than price, this would merely replicate the price-disconnect failure in these markets. The price disconnect is the problem, and A/B-rated substitution at the pharmacy counter is the cure. The generic-substitution regime is *designed* to render unprofitable active marketing of the product to doctors.

## V. ANTICOMPETITIVE CONDUCT

### A. Step 1: Improperly List the '394 Patent in the Orange Book Knowing That it Could Not Reasonably be Asserted Against a Generic Manufacturer.

110. On April 15, 2005, Warner Chilcott submitted NDA 21-871 seeking FDA approval to market what became known as Loestrin 24. The FDA approved the NDA on February 17, 2006.

111. As part of its NDA for Loestrin 24, Warner Chilcott submitted the '394 patent for listing in the Orange Book. The Hatch Waxman Amendments and FDA regulations expressly preclude NDA applicants from listing patents in the Orange Book that cannot "reasonably be asserted" against a manufacturer who makes, uses, or sells a generic version of the drug.

112. Warner Chilcott submitted the '394 patent for listing in the Orange Book, even though it knew that the '394 patent could not reasonably be asserted against generic Loestrin 24 manufacturers.

113. Before listing the '394 patent, Warner Chilcott knew that the claimed invention was obvious in light of the prior art, and thus it knew the patent could not withstand a challenge to its validity.

114. Before listing the '394 patent, Warner Chilcott knew that it was procured by fraud and inequitable conduct on the Patent and Trademark Office ("PTO"), and thus it knew that the '394 patent could not withstand a challenge to its enforceability.

115. Warner Chilcott's listing and later enforcement of the '394 patent was objectively and subjectively baseless. Warner Chilcott did not believe and could not reasonably have believed that the '394 patent could successfully be asserted against manufacturers of generic versions of Loestrin 24. By listing the '394 patent, Warner Chilcott forced potential generic competitors to file paragraph IV certifications and thus become subject to the entry barriers attendant upon those certifications.

**1. Loestrin's Active Ingredients Have Been Used Since the 1970s to Prevent Pregnancy.**

116. Traditional oral contraceptives contain 21 active tablets and 7 placebo tablets. Loestrin 24 contains 24 active tablets (containing 1 mg of norethindrone acetate and 20 μg of ethinyl estradiol) and 4 placebo tablets (containing ferrous fumarate). Warner Chilcott markets

Loestrin 24's longer, 24-day active tablet regimen as providing an effective low dose birth control associated with shorter, lighter periods with less bleeding.

117. The active ingredients in Loestrin 24, the hormones norethindrone acetate and ethinyl estradiol, are not protected by any patent. In fact, norethindrone and ethinyl estradiol have served as active ingredients in Loestrin-branded oral contraceptives since the early 1970s.

118. On April 30, 1973, the FDA simultaneously approved NDAs for drugs later known as Loestrin Fe 1.5/30 (NDA 017355) and Loestrin 1/20 (NDA 017354).[10] Both were approved as a method of oral contraception in women. Both provide a continuous dosage regimen consisting of 21 progestogen-estrogen oral contraceptive tablets and seven placebo ferrous fumarate tablets for the balance of the cycle. (We use the terms placebo, inactive, and iron pills interchangeably.)

119. The contraceptive tablets contain the active ingredients norethindrone acetate and ethinyl estradiol. The ferrous fumarate tablets are non-hormonal, and—according to the label—are present only to facilitate ease of drug administration via a 28-day regimen and do not serve any therapeutic purpose.

120. The label for Loestrin 24 refers to the inactive tablets as "reminder" pills. It instructs patients to THROW AWAY the reminder pills they missed (emphasis in original) if they forget to take one.

121. On October 1, 1976, the FDA approved two additional Loestrin formulations, Loestrin 21 1.5/30 (NDA 17875) and Loestrin 21 1/20 (NDA 17876) ("Loestrin 21"). The Loestrin 21 1.5/30 and Loestrin 21 formulations include only active tablets. The patient takes

[10] For all Loestrin products, the "Fe" is sometimes dropped from the name. "Loestrin Fe 1/20" and "Loestrin 1/20" refer to the same product. "Loestrin 24 Fe" and "Loestrin 24" refer to the same product.

one tablet daily for 21 consecutive days followed by one week of no tablets. This is described as "three weeks on – one week off."

122. The numerator in the fractions in the Loestrin drug products' names refers to the number of milligrams of norethindrone acetate contained in an active tablet. The denominator refers to the number of micrograms of ethinyl estradiol contained in an active tablet.

123. Loestrin 1/20 and Loestrin 21 both contain 21 of the same active tablets. The only difference between a pack of Loestrin 1/20 and a pack of Loestrin 21 is that the Loestrin 21 pack does not contain any placebo/iron tablets.

124. Loestrin 1.5/30 and Loestrin 21 1.5/30 both contain the same active tablets. The only difference between a pack of Loestrin 1.5/30 and Loestrin 21 1.5/30 is that the Loestrin 21 1.5/30 does not contain any placebo/iron tablets.

125. Generic versions of all four first-generation Loestrin products have been available for decades. Defendant Watson and generic manufacturer Barr Pharmaceuticals, Inc. sell, or used to sell, FDA-approved generic versions of all four products. Generic manufacturer Vintage Pharms LLC also sells, or used to sell, FDA-approved generic versions of Loestrin 1/20 and Loestrin 1.5/30 products.

126. Loestrin 24 contains the same active tablets as Loestrin 1/20 and Loestrin 21, but includes 24 active tablets in each pack (instead of the 21 active tablets contained in each pack of Loestrin 1/20 and Loestrin 21).

127. Warner Chilcott earned over $1.7 billion in revenue from branded Loestrin 24 sales through the end of 2012.

| **Year** | **Annual Net Revenue** |
|---|---|
| 2012 | $389 million |

| | |
|---|---|
| 2011 | $396 million |
| 2010 | $342 million |
| 2009 | $247 million |
| 2008 | $197 million |
| 2007 | $148 million |
| 2006 | $ 44 million |

**2. The ’394 Patent is Obvious in View of the Prior Art.**

128. The sole inventor of the ’394 patent is Dr. Gary D. Hodgen. Hodgen filed the application that led to the issuance of the ’394 patent on July 22, 1994. On September 26, 1994, Hodgen assigned the application to his employer, Eastern Virginia Medical School (“EVMS”). On October 2, 1994, EVMS assigned the application to Warner-Lambert Company LLC (for its Parke-Davis division). Warner-Lambert assigned the ’394 patent to Galen Holdings, PLC in March 2003. In July 2004, Galen Holdings PLC changed its name to Warner Chilcott PLC, and on August 1, 2004, that entity assigned the ’394 patent to Warner Chilcott Company, Inc.

129. In general, the claims of the ’394 patent are directed toward a method of female contraception involving administering a combination of an estrogen and a progestin in equivalent to certain concentrations and weight ratios of ethinyl estradiol and norethindrone acetate, respectively and at a weight ratio of at least 1:45 ethinyl estradiol and norethindrone acetate.

130. Breaking down the elements, the claims of the ’394 patent require a monophasic combined contraceptive method defined by the following limitations:

a. estrogen in a dosage amount of either the equivalent of about 1 to 35 mcg of ethinyl estradiol (Claim 1) or up to 30 mcg of ethinyl estradiol per active pill (Claim 12);

b. progestin in a dosage amount of either the equivalent of about 0.025 to 10 mg of norethindrone acetate (Claim 1) or the equivalent of about 0.5 to 1.5 mg of norethindrone acetate (Claim 7) per active pill;

c. the estrogen and progestin are at a weight ratio of at least 1:45 ethinyl estradiol to norethindrone acetate (Claim 1) or a weight ratio of at least 1:50 ethinyl estradiol to norethindrone acetate (Claim 8); and

d. a 23-25 consecutive day dosing regimen (Claim 1) or a 24 consecutive day dosing regimen (Claim 9).

131. All claims of the ’394 patent are invalid for obviousness because the differences between the patented subject matter and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.

132. WO 93/17686 (“the ’686 publication”), U.S. Patent No. 5,108,995 (“the ’995 patent”), and U.S. Patent Number 4,826,831 (“the ’831 patent”) teach doses of ethinyl estradiol that fall within the claimed ranges and weight ratios of the ’394 patent.

133. More specifically, Loestrin 1/20 contains the specific estrogen and progestin compounds recited in the claims of the ’394 patent, in the claimed amounts and in the claimed weight ratios. The only meaningful difference is that the active tablets in Loestrin 1/20 are taken for 21 days, not the 23-25 days contemplated by the ’394 patent.

134. Nevertheless, European Patent No. 0253607 (“the ’607 patent”) discloses a 24-day dosing regimen and the ’686 publication teaches an extended regimen.

135. Because all the limitations within the ’394 patent are disclosed in the prior art, the question simply becomes whether one of skill in the art would be motivated to combine the prior art references and derive the claimed subject matter with a reasonable expectation of success. The prior art easily provides such motivation.

136. There are examples in the prior art of other 24-day regimes that are safe and effective. One of ordinary skill would thus have expected that administering a combination of estrogen and progestin for 23-25 days, or specifically for 24 days, would be safe and effective.

137. Moreover, the prior art demonstrates a specific and well-recognized concern with traditional 21/7 combination oral contraceptive regimens, particularly for those such as the claimed preparation in the '394 patent that rely on low-dose ethinyl estradiol. The prior art demonstrates that the unregulated ovarian activity that occurs during a seven-day pill-free interval (or hormone free interval ("HFI")) leads to follicular development, which can lead to pregnancy, and those references also explain that patients inadvertently extending the HFI by missing one or more pills could lead to escape ovulation and unintended pregnancy. And the risk of "missed pill" ovulation is inversely related to a user's daily estrogen dosage; the lower the dosage, the greater the risk.

138. Several prior art references not only illuminate the problem, but also expressly propose the solution. The prior art directly recommends use of 24/4 and 23/5 dosing regimens specifically to minimize the risks of escape ovulation. B.G. Molloy et al., *"Missed Pill" conception: fact or fiction?*, 290 Brit. Med. J. 1474, 1475 (1985) ("Molloy") ("To reduce the risk of missed pill conception a 28 day pack containing 23 pills and 5 blanks could be substituted for the current 21 day pack. This would still permit a withdrawal bleed without the risk of significant follicular development.") N.D. Goldstuck et al., *Use and misuse of oral contraceptives by adolescents attending a free-standing clinic*, 3 Advances in Contraception 335, 338 (1987) ("Goldstuck") ("The suggestion [for 24/4 dosing] is of considerable merit. This would both maintain a 28–day regimen and help reduce the pill-free interval in those women who inadvertently miss a pill."); John Guillebaud, *The forgotten pill—and the paramount importance*

*of the pill-free week*, 12 Brit. J. Fam. Plan. 35, 43 (1987) ( "Guillebaud") ("[I]t is preferable to shorten the pill-free interval, usually to four days, in women where there is a suspicion of an increased risk of breakthrough ovulation.")

139. The prior art's direct recommendations to use 24/4 and 23/5 dosing regimens to minimize the risks of escape ovulation would have motivated one of ordinary skill in the art to implement such a shortened pill-free interval for use with known low-dose products such as what is recited in the claims of the '394 patent.

140. Moreover, the prior art also proposes to provide improved suppression of follicular development by using a 24-day regime of active tablets in oral contraceptive products while incrementally increasing the progestin. This too would have motivated one of ordinary skill in the art to implement the claimed dosing regimen in the '394 patent. The prior art further highlights a concern that a seven-day tablet-free interval may be associated not only with diminished contraceptive efficacy, but also symptoms of estrogen withdrawal, for example, migraine headaches. The prior suggests that the seven-day tablet-free interval could be shortened to achieve relief from such symptoms.

141. The prior art also suggests that the incidence of intermenstrual bleeding—a side effect of some oral contraceptives—might, theoretically, be reduced by giving an additional combination tablet in each cycle.

142. Simply put, given all the plain disclosures and clear motivation to combine those disclosures in the prior art, no reasonable litigant would expect to successfully assert the '394 patent against a generic Loestrin 24 competitor because it would be found invalid for obviousness.

### 3. The ’394 Patent Is Unenforceable.

143. The ’394 patent is also unenforceable, in light of equitable doctrines, including inequitable conduct, common law fraud, and unclean hands.

144. Under 37 C.F.R. § 1.56 and common law, all persons involved in the prosecution of a U.S. patent application have an affirmative duty of candor and good faith to the PTO. The applicants for the ’394 patent, including Hodgen, counsel, and others substantially involved in its prosecution (collectively, the “applicants”), breached their duty by intentionally misrepresenting material facts, failing to disclose material information, and submitting false information to the PTO with the intent to deceive.

145. In pursuit of the patent, the applicants knowingly defrauded the PTO through a series of acts and omissions that include:

a. concealing from the PTO the prior invalidating public use of the claimed subject matter during a clinical study;

b. making false and material statements to the examiner during prosecution of the application; and

c. intentionally withholding material invalidating prior art from the PTO.

146. But for the applicants’ knowingly fraudulent acts and omissions, the PTO would have never issued the ’394 patent.

#### a. Intentional Concealment of Prior Public Use

147. The applicants knew about a clinical study conducted publicly and more than one year before the ’394 patent’s filing date. The study employed the method recited within the claims of the ’394 patent. Even though the study was material to the patentability of the claims of the ’394 patent, the applicants intentionally concealed the study from the PTO in order to

secure the '394 patent, thereby committing inequitable conduct and rendering the patent unenforceable.

148. Beginning as early as January 1993, scientists at EVMS conducted a clinical study involving women participants who took tablets of the oral contraceptive Loestrin 1/20 for 25 consecutive days of the 28-day cycle ("the study"). The participants in the study knew they were taking Loestrin 1/20 tablets for 25 consecutive days of the 28 day cycle. The participants were also under no confidentiality restrictions about the method used in the study.

149. During the time of the clinical trial in 1993, Parke-Davis (a division of Warner-Lambert) commercially marketed Loestrin 1/20 in the United States.

150. Hodgen, as well as Roger Boissonneault (the former Vice President of Female Health Care at Parke Davis and later President and CEO of Warner Chilcott), were both aware of the study.

151. In a letter proposing a "technology transfer agreement" with Parke Davis in 1993, Hodgen explained to Boissonneault why Hodgen believed that Parke Davis should pay EVMS for the "technology" used in the study.

152. The applicants intended to conceal the study, which they had a duty to disclose to the PTO during the prosecution of the '394 patent.

153. The study is material to the patentability of the '394 patent as a public use of one or more claims of the '394 patent.

154. The applicants did not disclose the study to the PTO during the prosecution of the '394 patent.

155. Boissonneault was instrumental in acquiring the '394 patent, first for Park Davis while the application was pending and then for Warner Chilcott after the patent issued. After

Hodgen's letter, on October 2, 1994, EVMS assigned ownership of the application to Boissonneault's then-employer, Warner Lambert (the corporate parent of Parke Davis). In September 2000, Boissonneault was appointed Chief Executive Officer and Director of Warner Chilcott's predecessor, and in March 2003, Warner Lambert assigned the '394 patent to the predecessor known today as Warner Chilcott, where Boissonneault was Chief Executive Officer, President, and Director from 2005 until 2013.

156. Warner Chilcott, before submitting the '394 patent to the FDA for submission in the Orange Book, knew of the study. Warner Chilcott knew that the study was material to the patentability of the '394 patent and that the applicants knowingly did not disclose the study. Warner Chilcott knew or reasonably should have known that the '394 patent would be ruled unenforceable in patent litigation for this very reason.

**b. False Statements and Material Withholding of Information Concerning Amount of Estrogen in Prior Art Oral Contraceptives**

157. The originally-filed patent application that eventually led to issuance of the '394 patent claimed, inter alia, a method of using an oral contraceptive containing 5–35 mcg of ethinyl estradiol and 0.025 to 10 mg of norethindrone acetate for 23–25 consecutive days of a 28 day cycle.

158. The '607 patent discloses a method of using an oral contraceptive for at least 23 days of a 28 day cycle.

159. Craft, I.L., T.J. Peters, "Quantitative changes in plasma amino acids induced by oral contraceptives," Clin. Sci. (1971), 41(4), 301-07 ("Craft") discloses an oral contraceptive combining 50 mcg of ethinyl estradiol and 3 mg of norethindrone acetate.

160. By an Office Action mailed January 23, 1995, the PTO rejected pending claims 1-12 of the original application as being unpatentable under 35 U.S.C. § 103 as obvious over Craft in view of the '607 patent.

161. In response to the January 23, 1995 Office Action, the applicants made several misrepresentations to the PTO. The applicants wrote on July 19, 1995:

> [T]he claimed regimen leaves the patient with a total estrogen exposure per annum **which is well below the total annual dose of estrogen in all other combination formulations commercially available in this country. Those all contain at least 30 mcg [ethinyl estradiol]** (Craft uses 50 mcg) and a regimen of 21 dosing days plus a 7-day pill free interval. With the claimed method, although there are more treatment days per year at say 20 mcg [ethinyl estradiol] per day, the total drug exposure on a yearly basis remains significantly below the amount in an estrogen/progestin combination oral contraceptive which contains 30 or more mcg [ethinyl estradiol] daily.
>
> (emphasis added.)

162. The applicants knew that these representations were false. They knew that Loestrin 1/20 tablets contained 20 mcg of ethinyl estradiol and were commercially available in the United States, and that other 20 mcg ethinyl estradiol oral contraceptives were available in Europe. The applicants also knew that Loestrin 1/20 exposes a woman to half as much estrogen annually (5.5 mg) than the dosing regimen claimed in the '394 patent, which may be as high as 11.4 mg.

163. The amount of estrogen used in prior art combination formulas is material to the patentability of the claims of the '394 patent. Following the applicants' July 19, 1995 response to the PTO, the PTO issued on November 28, 1995 a final rejection of the pending claims based on the Craft and '607 patent references. In the PTO's final rejection, the PTO stated that the difference between the estrogen amount claimed in the '394 patent and disclosed by the prior art was not patentable, writing:

> Claim 1 recites a possible dosage of 35 mcg of estrogen which is only 15 mcg lower than the 50 mcg dosage taught by Craft et al. It has not been demonstrated that a dosage regimen differing by only 15 mcg less of estrogen has unexpected contraceptive and reduced breakthrough bleeding results.

164. The PTO expressly found that the Craft disclosure of 50 mcg of estrogen rendered the claims of the application leading to the '394 patent obvious.

165. The applicants intended to deceive the PTO by falsely stating that all U.S. oral contraceptives contain at least 30 mcg of estrogen and expose women to higher annual dosages than the claimed dosing regimen when they knew that prior art oral contraceptives in both the U.S. and Europe contain 20 mcg of estrogen, and may expose women to half as much estrogen annually than that which was claimed in the application.

**c. Intentional Withholding of Prior Art That Teaches a Regimen of More Than 21 Days for Oral Contraceptives**

166. The applicants intentionally concealed prior invalidating art, cited above as Molloy.

167. As shown above, the Molloy reference is a critical piece of prior art. It illuminates a specific problem and proposes a solution that directly motivates one skilled in the art to implement the 23-25 day dosing regimen as claimed by the '394 patent. In Molloy, the author states: "To reduce the risk of missed pill conception a 28 day pack containing 23 pills and 5 blanks could be substituted for the current 21 day pack. This would still permit a withdrawal bleed without the risk of significant follicular development." Because it teaches one skilled in the art to increase a 21 day schedule of commercial oral contraceptives to 23 days, Molloy is clearly material to the patentability of the claims of the '394 patent.

168. Both Hodgen and Warner Chilcott were aware of the Molloy reference, as shown by a letter Hodgen wrote to Warner-Lambert in December 1990. The applicants never disclosed

Molloy to the PTO during the prosecution of the '394 patent, and intended to deceive the PTO by withholding Molloy from consideration during the examination of the '394 patent claims.

169. Warner Chilcott knew that the applicants procured the '394 patent fraudulently before it listed the '394 patent in the Orange Book for Loestrin 24, and before it asserted the patent in lawsuits filed against Watson, Lupin, and Mylan.

### B. Step 2: Assert the '394 Patent in Sham Litigation Against Generics and Conspire to Delay Their Entry into the Loestrin 24 Market.

170. Because the '394 patent claims only a narrow method (i.e., a few extra days worth of tablets) of administering the same combination of the same active ingredients that have been used for decades to prevent pregnancy, generic manufacturers were eager to apply for FDA approval to market generic versions of Loestrin 24 long before the expiration of the '394 patent.

171. Warner Chilcott knew that it would be unable to obtain a court ruling that the claims of '394 were valid and infringed by the generics' products. Indeed, the Court of Appeals for the Federal Circuit would later rule that there was no genuine issue of fact that a similar, earlier filed patent—claiming the same 23-25-day regimen for another decade-old oral combination contraceptive manufactured by a Bayer—was invalid based on the same theories asserted by some of the same generics in the Loestrin 24 litigation. The Court of Appeals held the patent was obvious in view of the same invalidating prior art that Warner Chilcott knew the '394 patent's applicants intentionally withheld from the PTO.

172. Warner Chilcott knew that it would not be able to exclude competitive entry based solely on the strength of the '394 patent. Instead, Warner Chilcott prosecuted sham litigation against generic ANDA filers and, under the guise of patent settlements and business deals, conspired with those same generics to delay generic competition until the near end of the patent's 2014 expiration date.

**1. Warner Chilcott Prosecutes the '394 Patent in Sham Litigation Against Watson.**

173. On or about June 19, 2006, Watson notified Warner Chilcott that Watson had filed ANDA 78267 in order to market a generic version of Loestrin 24. Watson's notice letter included a paragraph IV certification that the commercial manufacture, use and/or sale of its generic Loestrin 24 product would not infringe any valid claim of the '394 patent.

174. On July 28, 2006, Warner Chilcott sued Watson in the United States District Court for the District of New Jersey, alleging that Watson's generic Loestrin 24 product would infringe the '394 patent. Warner Chilcott's purpose in filing the lawsuit was to delay generic competition as long as possible.

175. In Watson's paragraph IV notice letter, Watson provided Warner Chilcott with compelling reasons why the '394 patent is invalid in view the prior art. During the litigation, Watson also uncovered during discovery a host of defenses that further supported the invalidity of the '394 patent, as well as evidence exposing the '394 applicant's wrongful conduct before the PTO, including the intentional withholding of Molloy and the 1993 study, as well as other intentional misstatements regarding the prior art. On January 23, 2008, Watson filed an amended answer and counterclaim aggressively asserting defenses/counterclaims that relied on theories of obviousness and unenforceability. Those theories advanced a compelling case against Warner Chilcott's '394 patent, which Warner Chilcott knew it would not be able to overcome.

176. A reasonable pharmaceutical manufacturer in Warner Chilcott's position could not realistically expect to succeed on the merits of its infringement suit against Watson. Warner Chilcott faced a substantial battle. Watson was attacking the only patent providing any coverage for Loestrin 24—a then $200 million a year drug—on three separate fronts: invalidity, unenforceability, and non-infringement. It was a near certainty that a court would adjudge the

'394 patent invalid and/or unenforceable. So Warner Chilcott decided to pay Watson to stay out of the market.

**2. Warner Chilcott and Watson Enter an Exclusion Payment Agreement.**

177. On or about January 12, 2009, Warner Chilcott and Watson entered into an Exclusion Payment Agreement. Pursuant to that Agreement, Warner Chilcott ended its '394 patent litigation against Watson, and Watson dropped its defenses/counterclaims against Warner Chilcott. At the time of the unlawful Agreement, the court hearing the patent case had not issued any substantive rulings regarding the merits of the case.

178. Under the Agreement, Watson agreed to delay launching its generic Loestrin 24 until January 22, 2014.

179. As the quid pro quo for Watson's agreement to drop its challenge to the '394 patent and to delay marketing its generic Loestrin 24, Warner Chilcott agreed to pay Watson substantial sums. Warner Chilcott's payments to Watson under the Agreement took at least five forms.

180. *First*, the Agreement prohibits Warner Chilcott from launching an authorized generic version of Loestrin 24 during Watson's first 180 days of marketing. The Agreement expressly prohibits Warner Chilcott or its affiliates from marketing or supplying, or granting any third party rights to market, an authorized generic during the 180-day period. Absent the no-AG clause, Warner Chilcott had the incentive and ability to launch an authorized generic version of Loestrin 24. Warner Chilcott/Actavis frequently marketed authorized generic versions of their branded counterparts, and have done so with respect to at least the following drugs: Actonel, Actigall, Atelvia, Condylox, Doryx tablets, Emla, Femhrt, Kadian (in at least 7 strengths), Microzide, Norinyl, Nor-Qd, and Tenuate (2 formulations).

181. A No-AG clause's value to Watson is readily calculable using the known economics of the pharmaceutical industry. Before the Exclusion Payment Agreement, Loestrin 24 had annual U.S. sales of approximately $200 million. The difference in revenue for Watson without a No-AG pact, and with a No-AG pact, is calculated as follows:

a. Six months (180 days) of Loestrin 24 sales generate revenue to Warner Chilcott of $100 million (6/12 * $200 million).

b. With a No-AG clause, Watson would likely take 78% (or more) of the brand's unit sales during those six months. Thus, Watson would capture approximately $78 million worth of brand units during those six months ($100 million * 0.78).

c. With only one generic on the market, the first-filer typically prices its product at a 10% off the brand's price. This would result in generic sales revenues during the 180-day period of approximately $70.2 million ($78 million * 0.9).

d. Those revenues would be dramatically lower, however, if Watson faced competition from an authorized generic during those six months. An FDA study concludes that the addition of a second generic drives the average generic price down from a 10% discount off the brand price to a 26% discount off the brand price. Thus, while generics would still take78% of brand unit sales during the six months, the dollar value of those generic sales would drop from $70.2 million to $57.72 million ($78 million * .74).

e. Watson would not get all of those revenues, however. Instead, the unit sales of the generic during the six months would be split (roughly evenly) between Watson and Warner Chilcott's authorized generic. In fact, the authorized generic often captures more than half of the unit sales due to a "first-mover" advantage and other marketing advantages. Without a No-AG clause, Watson's revenues during the six months would be at most $28.86 million ($57.72 million * .5).

f. Thus, the value of a No-AG clause to Watson is at least $41.34 million ($70.2 million - $28.86 million). That is the amount of the pay-off from Warner Chilcott to Watson accomplished via the No-AG clause.

182. *Second*, as part of the Agreement Warner Chilcott granted to Watson an exclusive license (exclusive even against Warner Chilcott) to market and sell throughout the world a branded oral contraceptive, later named Generess, that was then in late-stage development.

Warner Chilcott also provided Watson a non-exclusive license to make a version of Generess ("Generess license agreement"). Under the license agreement, Warner Chilcott agreed to complete Phase III clinical trials and obtain FDA approval of the NDA. Watson was then entitled to exclusively commercialize Generess. In exchange, Watson agreed to pay Warner Chilcott a [redacted]. Warner Chilcott also granted Watson an exclusive supply agreement for Warner Chilcott to fully manufacturer, package, and supply Generess to Watson at a price to Watson of [redacted] ("Generess supply agreement" and collectively with the Generess license agreement, the "Generess Payment")

183. The Generess Payment, both expected and actual, was of extraordinary value to Watson. The parties understood that, given Generess's three-year new-product exclusivity and Warner Chilcott's patents, the Generess Payment provided Watson a significant cash value commensurate with the supracompetitive profits that come with selling a branded drug without generic competition for several years. In fact, after Watson launched NDA 022573 for Generess on or about April 25, 2011, it faced no generic competition for nearly fours (until April 1, 2015), during which time Generess generated sales of over $268 million. Branded Generess sales after generic entry through February 2016 were nearly $17 million, during which time Watson also launched an authorized generic that generated an additional $11 million. Gross sales attributable to the Generess Payment from launch through February 2016 have been nearly $300 million.

184. Watson's acceptance of the Generess agreements was conditioned on and in exchange for Watson's agreement to delay generic competition for Loestrin 24. The agreements

were executed on the same day that Watson agreed to settle the Loestrin 24 patent litigation and delay its market entry, and both agreements were announced together in a single press release. It is a common practice in the pharmaceutical industry, after cash payments drew attention of the FTC and Congress, for brand manufacturers to disguise a payment for delay through a concurrently executed business deal, such as the Generess Payment.

185. In addition, the Generess Payment cannot be justified solely as compensation for the services to be performed by Watson under the deal. The terms of the Generess Payment made no business or economic sense for Warner Chilcott absent Watson's agreement to preserve Warner Chilcott's monopoly and not compete with Loestrin 24. The terms enabled Watson to maintain at least [redacted] gross margin and provided Warner Chilcott a mere [redacted]. The Generess Payment also included other terms unduly beneficial to Watson, such as [redacted]. But for Watson's agreement to delay entering with generic Loestrin 24, Warner Chilcott would not have provided Watson the Generess Payment or would not have provided it on such favorable terms to Watson.

186. *Third*, the Agreement provides that Warner Chilcott will pay Watson annual fees and a percentage of net sales above a specified level in connection with Watson's co-promotion of Femring, a Warner Chilcott hormone therapy product, from January 9, 2009, through December 31, 2011. Watson performed a defined set of promotion services, and Warner Chilcott paid Watson: [redacted]

[redacted] The Femring co-promotion agreement provided compensation to Watson that was in excess of the fair value of the promotional services that Watson was required to perform.

187. *Fourth*, Warner Chilcott agreed not to grant a license to any other manufacturer to enter with a generic version of Loestrin 24 until at least 180 days after Watson entered the market. Warner Chilcott thus guaranteed to Watson a period of 180 days of exclusivity as the only generic Loestrin 24 on the market, absent another generic manufacturer outlasting a 30-month stay or obtaining a court order permitting such entry. At the time of the settlement, Watson knew that it likely forfeited its 180-day exclusivity. Watson knew that the FDA received its ANDA on April 17, 2006, and never granted tentative approval within the required 30 months, by October 17, 2008. 21 U.S.C. § 355(j)(5)(D)(i)(IV). Watson also knew that the requirements for approval of its ANDA were not changed or reviewed after its ANDA was filed, nor was a related citizen petition submitted that would extend the 30-month period. 21 U.S.C. § 355(q)(1)(G). Months later on September 1, 2009 (when Watson's ANDA received approval), the FDA ruled that Watson in fact did forfeit its right to 180 days of marketing exclusivity. Thus, the contractual exclusivity granted by Warner Chilcott had substantial value to Watson.

188. *Fifth*, Warner Chilcott agreed to pay Watson in the form of a valuable "acceleration clause."[11] The acceleration clause provided that (1) if any other generic

[11] To be precise, Warner Chilcott provided Watson three acceleration clauses in paragraphs 5, 7, and 8 of Watson's Settlement and License Agreement to cover the three scenarios in which another generic manufacturer could potentially enter the market earlier than Watson. All three acceleration clauses had the same purpose and effect of (1) deterring other generic manufacturers from entering earlier than Watson and (2) compensating Watson to delay

manufacturer entered the market before Watson's licensed entry date (either at-risk of patent infringement or upon winning the patent litigation through appeal), then Watson's entry date would be accelerated accordingly,[12] and (2) if Warner Chilcott agreed to provide any other generic manufacturer an entry date earlier or within 180 days after Watson's, then Watson's entry would be accelerated to 180 days before that other generic's entry date.

189. Given Watson's agreeing to a substantially delayed licensed entry date, absent the acceleration clause, other generic manufacturers would have had an opportunity and incentive to enter the market before Watson's scheduled entry date of January 22, 2014 and thereby obtain for themselves a period of *de facto* exclusivity as the only ANDA-based generic Loestrin 24 on the market. Another generic manufacturer could have entered earlier than Watson by either: (1) waiting out a 30-month stay and then entering the market "at risk" while the patent case was pending; (2) litigating and winning the patent case; or (3) leveraging the strength of its patent challenge to negotiate an earlier licensed entry date.

190. The acceleration clause was of substantial value to Watson because it guaranteed that no later generic filer would enter earlier than Watson, preserving the very 180-days of exclusivity that Watson forfeited. By eliminating the possibility of obtaining a period of *de facto* exclusivity, the clause very substantially diminished, if not altogether eliminated, the incentive for later generic filers to enter before January 22, 2014.

191. In a joint press release following the settlement, Warner Chilcott and Watson agreed to publicly announce that Watson may enter on either "January 22, 2014 or the date on

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its entry. Thus, for ease of reference, Plaintiffs refer to these three provisions collectively as the "acceleration clause."

[12] The parties stipulated that if the acceleration clause is triggered by an at-risk launch, Watson's entry license terminates if the other manufacturer subsequently exits the market—confirming that the acceleration clause's only intended function is deterring other manufacturers' entry.

which another generic version of Loestrin® 24 Fe enters the U.S. market." The parties also agreed that Warner Chilcott could disclose the specific terms of Watson's acceleration clause to successive Loestrin 24 ANDA filers. The purpose in publicly and privately disclosing the acceleration clause was to deter or dampen successive filers from obtaining an earlier entry date than Watson's.

192. The acceleration clause did in fact have the intended effect of deterring later filers from attempting to enter before Watson's publicly announced licensed entry date of January 22, 2014.

193. As set forth below, Lupin agreed not to enter earlier than January 22, 2014. Rather than strive for an earlier entry date, Lupin accepted payments and settled its patent suit with a licensed entry date on July 22, 2014—the expiration date of the '394 patent and 180 days after Watson's. Importantly, Lupin's settlement agreement did not contain the acceleration clause that Warner Chilcott provided Watson. So when Mylan subsequently filed its ANDA, it was not deterred from entering earlier than Lupin's licensed entry date, only Watson's. Mylan agreed not to enter earlier than January 22, 2014 (Watson's entry date), but still competed for and obtained a licensed entry date of July 1, 2014—earlier than Lupin's entry date.

194. But for the anticompetitive effects of the acceleration clause, later filers, such as Lupin and Mylan, would have entered or obtained licensed entry dates earlier than January 22, 2014. Absent Warner Chilcott providing Watson the acceleration clause, Watson would not have settled for an entry date as late as it did; Watson would have entered earlier than January 2014.

195. All of these payments had substantial value to Watson, and Watson could not have obtained any of these payments even if it had won the patent litigation against Warner Chilcott.

196. Warner Chilcott made these payments in exchange for Watson's agreement to delay generic competition to Loestrin 24 for more than four years. Absent Watson's agreement to delay entry into the market with generic Loestrin 24, Warner Chilcott would not have agreed to make these payments. And absent the payments, Watson would not have agreed to delay entry into the market. Warner Chilcott paid Watson for delayed market entry of generic Loestrin 24.

197. These payments far exceed the costs of continuing to litigate the settled patent infringement litigation. Studies show that litigation of a patent infringement suit of this nature, from complaint to verdict, costs between $6 and $10 million. Warner Chilcott's future expected litigation costs at the time of the settlement with Watson were much less than that because, among other reasons, the patent case had been pending for years.

198. There are no other procompetitive benefits, countervailing efficiencies, or increases in consumer welfare from Watson's Exclusion Payment Agreement that outweigh the significant competitive harm caused by eliminating the risk of generic Loestrin 24 entry until January 2014.

**3. Warner Chilcott Files Sham Paragraph IV Litigation Against Lupin.**

199. As the first-filer, Watson had an opportunity to earn 180 days of exclusivity under the Hatch-Waxman Amendments. That circumstance created an economic incentive for other generic manufacturers to delay filing their own challenges to the '394 patent while Watson litigated against Warner Chilcott. If Watson had obtained an order finding the patent invalid or unenforceable, other generic manufacturers would have benefitted from that ruling without having to incur the costs of patent litigation.

200. On or about July 31, 2009, six months after the announcement of the Warner Chilcott/Watson agreement, Lupin notified Warner that Lupin had filed ANDA No. 091398, seeking to market generic versions of Loestrin 24. Lupin's notice letter included a paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid and enforceable claim of the '394 patent.

201. On or about September 9, 2009, Warner Chilcott sued Lupin for infringement of the '394 patent in the United States District Court for the District of Delaware (Civil Action No. 09-00673).

202. Warner Chilcott's timely filing of the lawsuit imposed on Lupin a 30-month stay of FDA approval that would not expire until on or around January 31, 2012.

203. Warner Chilcott filed the case against Lupin without regard to its merits. Simply by filing the case, Warner Chilcott obtained automatic exclusion of Lupin from the market for 30 months. Warner Chilcott's purpose in filing the case was to get the 30-month hiatus from generic competition, regardless of whether it ultimately won the case. In fact, had the case proceeded to a litigated conclusion, Warner Chilcott would have lost.

204. For the reasons set forth in detail above, Warner Chilcott's patent infringement litigation against Lupin was a sham.

205. Lupin answered the complaint on October 21, 2009, and alleged special defenses, including invalidity of the '394 patent and non-infringement.

206. To prevent generic entry using just the '394 patent, Warner Chilcott would have had to defeat each of Lupin's arguments regarding invalidity and prove that Lupin infringed the '394 patent. Warner Chilcott instead decided to protect its supracompetitive profits by paying Lupin to withdraw its challenges to the validity and enforceability of the '394 patent and delay

its introduction of generic Loestrin 24. And that is precisely what it did, in concert with both Watson and Lupin.

**4. Warner Chilcott and Lupin Enter an Exclusion Payment Agreement.**

207. To avoid the risk that the court would find the '394 patent invalid and/or not infringed, Warner Chilcott also unlawfully paid Lupin, pursuant to the Exclusion Payment Agreement, to drop its patent challenge and stay out of the market until after Watson's entry.

208. On or about October 10, 2010, before the close of fact discovery and before the court could issue any substantive rulings, Warner Chilcott induced Lupin to join its conspiracy with Watson. Pursuant to the Agreement, Lupin agreed to drop its challenge to the invalidity of the '394 patent and not compete with generic Loestrin 24 until after patent expiration—July 22, 2014.

209. It was not in Lupin's independent self-interest to delay its generic entry until July 22, 2014. For Lupin to accept such a delayed entry date without conspiring with Warner Chilcott and Watson, Lupin would have had to assess its likelihood of success on the patent merits—before any meaningful discovery developed—and legitimately believe that it had a 0% chance of succeeding in the litigation. No reasonable generic would file a paragraph IV certification and commit to patent litigation with the expectation of delaying entry until patent expiration, especially given the extraordinary weakness of the '394 patent. Neither Lupin nor Warner Chilcott believed that Warner Chilcott could exclude Lupin from the market until July 22, 2014 based solely on the strength of the '394 patent.

210. In order for Lupin to agree to delay its entry until after patent expiration, Warner Chilcott used both "carrots and sticks."

211. The "sticks" included the acceleration clause that Warner Chilcott and Watson conspired to place in Watson's agreement. While the specific terms of Watson's agreement were

bound by a confidentiality agreement, Watson and Warner Chilcott agreed that Warner Chilcott could inform Lupin and any other ANDA filer of the terms of the acceleration clause during settlement negotiations.

212. The purpose of sharing the acceleration clause with Lupin was twofold. First, it ensured that Lupin would know that no matter what licensed entry date it obtained, it would necessarily result in Watson accelerating its entry date 180 days earlier. This dampened, if not altogether diminished, Lupin's willingness to compete with Watson for an earlier negotiated entry date. Second, disclosing the acceleration clause enabled Warner Chilcott to credibly hold out from providing Lupin earlier licensed entry by claiming it would be "too expensive" for it to do so. The acceleration clause altered the incentives of both Warner Chilcott and Lupin so that they each would be "penalized" if Lupin entered sooner than Watson.

213. The "carrots" were the payments that Warner Chilcott offered to Lupin as a reward to commit to the conspiracy with Watson and delay generic competition. As the quid pro quo for Lupin's agreement to drop its challenge to the '394 patent and to delay entry of its generic Loestrin 24, Warner Chilcott agreed to pay Lupin substantial sums.

214. *First*, Warner Chilcott granted to Lupin, on an exclusive basis, to market, distribute, offer for sale, and sell a version of another branded oral contraceptive manufactured by Warner Chilcott—Femcon (the "Femcon Supply Payment"). Under the terms, Warner Chilcott would fully manufacture, package, and supply Femcon to Lupin for sale in the United States on the earlier of (i) 180 days after the Femcon "first-filer" entered the market (Teva Pharmaceutical Industries, Ltd, or its affiliates, under ANDA 78965), or (ii) January 1, 2013. Pursuant to the agreement, Lupin in fact entered the market as an authorized generic for Femcon in October 2011 (later marketed as WYMZYA Fe), and since that time has made over $35

million in gross sales—more than any other Femcon ANDA filer. But for Lupin's agreement to delay entry into the market for Loestrin 24, Lupin could not have begun making and selling generic Femcon under its own Femcon ANDA 091332 until at least January 31, 2012 (the expiration of the 30 month stay) and as late as March 23, 2016 (when Lupin obtained FDA final approval for ANDA 091332).

215. While Lupin and Warner Chilcott settled litigation concerning Femcon at the same time as Loestrin 24, the Femcon Supply Payment, on the provided terms, was not independent of Lupin's agreement to delay competing with Loestrin 24. The Femcon Supply Payment was attached to, and explicitly defined as being apart of, the settlement agreement concerning Loestrin 24. The Femcon Supply Payment would also only become effective upon dismissal of the Loestrin 24 litigation under the terms of the settlement agreement, and the Femcon Supply Payment could be terminated upon Lupin breaching its obligation to delay its market entry for Loestrin 24. The only reason for Warner Chilcott and Lupin to incorporate a supply agreement for Femcon as part of the Loestrin 24 settlement was to compensate Lupin for its agreement not to compete with generic Loestrin 24 until after expiration of the '394 patent.

216. In addition, the Femcon Supply Payment cannot be justified solely as compensation for the services to be performed by Lupin under the deal. The terms Warner Chilcott provided to Lupin made no business or economic sense for Warner Chilcott absent Lupin's agreement to preserve Warner Chilcott's monopoly and not compete with Loestrin 24. The terms required Warner Chilcott to fully manufacture, package, and supply Femcon to Lupin at a mere price to Lupin [redacted]. The usual and customary royalty rate in the pharmaceutical industry for an agreement such

as the this, executed at arms-length, would be 80%–90% of the generic's gross margin for units sold. But for Lupin's agreement to delay entering with generic Loestrin 24, Warner Chilcott would not have provided Lupin the Femcon Supply Payment or would not have provided it on such favorable terms to Lupin.

217. *Second*, Warner Chilcott provided Lupin, on an exclusive basis, the right to market, distribute, offer for sale, and sell in the United States a generic version of Asacol 400 mg (a branded treatment for inflammatory bowel disease), to be supplied by Warner Chilcott, contingent on another manufacturer launching a generic version of Asacol 400 mg in the United States. ("Asacol Supply Payment").

218. The Asacol Supply Payment had a substantial value to Lupin. At the time of the agreement, annual sales for Asacol 400 mg exceeded $400 million. While performance under the agreement is first contingent upon entry of another generic Asacol 400 mg, it is well understood in the pharmaceutical industry that generics typically deem it worthwhile to enter markets that have earned brand manufacturers as little as $20 million in annual sales. Given the relatively large size of the Asacol 400 mg market, at the time of the Lupin's settlement, Lupin had every reason to expect that generics would be motivated to enter, eventually triggering the opportunity for Lupin to earn substantial sales, all without the burden of having to file an ANDA and make the drug itself.

219. The Asacol Supply Payment was not independent of the Loestrin 24 settlement. They both were signed concurrently on October 14, 2010. Warner Chilcott and Lupin's Asacol Supply Payment is attached to, and explicitly defined as being apart of, the settlement agreement concerning Loestrin 24. The Asacol Supply Payment would only become effective upon dismissal of the Loestrin 24 litigation under the terms of the settlement agreement, and the

Asacol Supply Payment could be terminated upon Lupin breaching its obligation to delay its market entry for Loestrin 24. The settled litigation did not concern any patents that cover Asacol, and Lupin never filed an ANDA for Asacol 400 mg challenging its patents. The only reason for Warner Chilcott and Lupin to incorporate a supply agreement for Asacol as part of the Loestrin 24 settlement agreement was to compensate Lupin for its agreement not to compete with generic Loestrin 24 until after expiration of the '394 patent.

220. In addition, the Asacol Supply Payment cannot be justified solely as compensation for the services to be performed by Lupin under the deal. The terms of the Asacol supply agreement, mirroring those of the Femcon supply agreement, made no business or economic sense for Warner Chilcott absent Lupin's agreement to preserve Warner Chilcott's monopoly and not compete with Loestrin 24. The terms required Warner Chilcott to fully manufacture, package, and supply Asacol 400 mg to Lupin at a mere price to Lupin [redacted] The usual and customary royalty rate in the pharmaceutical industry for an agreement such as this, executed at arms-length, would be 80%–90% of the distributor's gross margin for units sold. But for Lupin's agreement to delay entering with generic Loestrin 24, Warner Chilcott would not have provided Lupin this Asacol Supply Agreement or would not have provided it on such favorable terms to Lupin.

221. *Third*, Warner Chilcott provided Lupin with $4 million in cash.

222. These payments had substantial value to Lupin, and Lupin could not have obtained any of these payments even if it had won the patent litigation against Warner Chilcott.

223. Warner Chilcott made these payments in exchange for Lupin's agreement to delay generic competition to Loestrin 24 for nearly four years. Absent Lupin's agreement to delay entry into the market with generic Loestrin 24, Warner Chilcott would not have agreed to make these payments. And absent the payments and Watson's acceleration clause, Lupin would not have agreed to join the conspiracy and delay entry into the market. Warner Chilcott paid Lupin, in conspiracy with Watson, for delayed market entry of generic Loestrin 24.

224. The collective value of these payments far exceed the costs of continuing to litigate the settled patent infringement litigation.

225. There are no other procompetitive benefits, countervailing efficiencies, or increases in consumer welfare from these payments that outweigh the significant competitive harm caused by eliminating the risk of generic Loestrin 24 competition.

**5. Warner Chilcott's Sham Litigation and Watson's Acceleration Clause Deter Mylan from Competing for Entry Earlier than 2014.**

226. Warner Chilcott and Lupin settled each of the Loestrin 24 and Femcon Fe litigations without Warner Chilcott providing Lupin an acceleration clause. Unlike Watson's agreement, Lupin's agreement does not permit Lupin to enter upon a third party successfully overcoming the '394 patent in litigation. Also unlike Watson's agreement, Lupin's agreement does not permit Lupin to enter earlier in the event another generic obtains an earlier licensed entry date. The only permissible basis under the agreement for Lupin to enter the market earlier than July 22, 2014 would be in the event a third party launched a generic Loestrin 24 product at-risk. However, if Lupin elected to enter after an at-risk launch, unlike Watson's entry under its agreement, Lupin's entry would be deemed "at-risk," preserving the right for Warner Chilcott to re-assert claims of patent infringement against it. Thus, while Watson's acceleration clause deterred or dampened the incentives of other ANDA filers to compete for an entry date sooner

than Watson's, there was no such effect on the incentives to compete for entry earlier than Lupin's.

227. On or about April 21, 2011, six months after the announcement of the agreement between Warner Chilcott and Lupin, Warner Chilcott received notice that Famy Care Ltd. together with Mylan Pharmaceuticals Inc. (collectively "Mylan") had filed ANDA 202742 for the purpose of marketing generic versions of Loestrin 24 before expiration of the '394 patent. Mylan's notice letter included a paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid and enforceable claim of the '394 patent.

228. On or about June 2, 2011, Warner Chilcott sued Mylan for alleged infringement of the '394 patent in the United States District Court for the District of New Jersey (3:11-cv-3262 (D.N.J.)).

229. Warner Chilcott's timely filing of its lawsuit imposed on Mylan a 30-month stay of FDA approval that would not expire until on or about October 21, 2013.

230. Warner Chilcott filed the case against Mylan without regard to its merits. Simply by filing the case, Warner Chilcott obtained automatic exclusion of Mylan from the market for 30 months. Had the case proceeded to a litigated conclusion, Warner Chilcott would have lost.

231. For the reasons set forth in detail above and below, Warner Chilcott's initial and continued prosecution of patent infringement litigation against Mylan was a sham.

232. Mylan answered the complaint on August 29, 2011 and asserted counterclaims and special defenses, including invalidity, unenforceability, and non-infringement of the '394 patent.

233. During discovery, Mylan, like Watson and Lupin before it, uncovered facts supporting a host of defenses that cast serious doubt especially on the validity and/or enforceability of the '394 patent.

234. On April 16, 2013, as discovery neared an end, the United States Court of Appeals for the Federal Circuit ruled in favor of Watson, Lupin, and other generics challenging the validity of U.S. Patent RE37,564 (the "'564 patent"). *Bayer Healthcare Pharm., Inc. v. Watson Pharm., Inc.*, 713 F.3d 1369 (Fed. Cir. 2013). The '564 patent, with an effective filing date earlier than the '394 patent,[13] was owned and asserted by Bayer Healthcare Pharmaceuticals, Inc. and affiliates ("Bayer"), the manufacturer of the combination oral contraceptive, Yaz.

235. Yaz like Loestrin 24, provides for a 24 day dosing regimen, with each tablet consisting of 20 mcg ethinyl estradiol. The primary difference between Loestrin 24 and Yaz, as well as the primary difference between the preparations claimed in the '394 and '564 patents, is that Yaz combines its 20 mcg of ethinyl estradiol with a different progestin (3 mg of drospirenone). But that difference, although critical for patients and doctors when selecting an appropriate birth control, was immaterial for the invalidity issues underlying the two drugs' patent lawsuits. Both drugs' respective combinations of ingredients were already disclosed in the prior art. The prior art also disclosed that extending the contraceptive regimen to 23-25 days is a solution to a frequently cited need by patients taking contraceptives. The issue in both patent cases, therefore, was simply whether a person of ordinary skill in the art would be motivated to combine the prior art references to come to the claimed 24-day regimen for the respective birth

[13] Bayer filed its first patent application directed to low-dose, extended-regimen combined oral contraceptives on December 22, 1993. That application was a foreign priority application filed in Germany. Bayer filed its first corresponding U.S. application in June 1994 and obtained U.S. Patent 5,824,667 (the "'667 patent") as a continuation of that first U.S. application on October 20, 1998. The '564 patent, issued on February 26, 2002, arose as a reissue of the '667 patent.

control products. In light of the "plain disclosures and express motivation to combine those disclosures in the prior art," the Federal Circuit held there was no genuine dispute as to any material fact that '564 was invalid for obviousness.

236. Notably, the Federal Circuit addressed the same arguments by some of the same generic manufacturers using essentially the same prior art that were involved in the Loestrin 24 litigation. Moreover, essential to the Federal Circuit's decision was its critical reliance on the very same invalidating prior art reference that was intentionally withheld by the '394 patent's applicants—the 1985 Molloy "missed pill" article.

237. With its patent case now certain to fail, Warner Chilcott nevertheless continued to assert the '394 patent in sham litigation against Mylan. On June 14, 2013, Warner Chilcott sought the "urgent assistance" of the court to exclude Mylan's invalidity expert, who served supplemental and reply reports in which he opined as to the invalidity of the '394 patent based on, among other things, the recent *Bayer* decision and its application of the "missed pill" prior art. On June 20, 2013, the court denied Warner Chilcott's request, finding that reports raised no theories on invalidity different than what was previously asserted by Mylan throughout the litigation: "that persons of ordinary skill in the art would have known that HFI in the oral contraceptive regimen could be modified by extending the administration of the combination pill and by doing this, persons of ordinary skill in the art would expect to decrease the amount of bleeding and reduce the chance of ovulation that could occur during the HFI."

238. Expert discovery closed soon thereafter, and the case was set for a bench trial to commence on August 12, 2013. Mylan submitted its trial brief on July 24, 2013.

239. The incentive for Mylan to continue to invest the time and resources into invalidating the '394 patent was substantially affected by three anticompetitive factors. First,

Mylan could not obtain FDA approval and enter at-risk because of Warner Chilcott's timely assertion and continuance of its sham litigation, which imposed on Mylan a 30-month stay of FDA approval that would not expire until the end of October 2013. Second, even if Mylan were to eventually enter, whether at risk or after a favorable court ruling, Watson's generic would enter contemporaneously pursuant to its acceleration clause. Third, no matter what licensed entry date Mylan could leverage from the strength of its underlying patent suit, Watson's entry would be accelerated 180 days sooner than Mylan's. After expiration of Mylan's 30-month stay, Watson's acceleration clause would dampen any remaining motivation that Mylan had to compete for an entry date earlier than January 2014.

240. On or about July 29, 2013, just weeks before a bench trial was scheduled to commence, Warner Chilcott settled the patent litigation with Mylan and the case was subsequently dismissed.

241. Notably, pursuant to the Warner Chilcott and Mylan agreement, Mylan agreed to drop its challenge to the '394 patent and accept a licensed entry date of July 1, 2014—three weeks before the licensed entry date of Lupin, who did not have an acceleration clause in its agreement.

242. Warner Chilcott also provided Mylan an acceleration clause, which permitted Mylan to enter earlier with a generic version of Loestrin 24 in the event another generic (other than under Watson's ANDA) entered earlier "with or without authorization" from Warner Chilcott.

243. But for Watson's anticompetitive acceleration clause, Mylan would not have agreed to a licensed entry date as late as it did; Mylan would have either leveraged the strength

of its patent suit to obtain a licensed entry date earlier than January 22, 2014 or continued to litigate to a favorable judgment.

### C. Step 3: Force Doctors and Patients to Switch Prescriptions from Loestrin 24 to Minastrin 24 before Entry of Generic Loestrin

244. With the prospect of generic competition looming in 2014, Warner Chilcott implemented another aspect of its anticompetitive scheme. Before manufacturers of generic Loestrin 24 could begin marketing their products, Warner Chilcott reformulated Loestrin 24 into another product, Minastrin 24, with the purpose and effect of preventing generic Loestrin 24 from being substitutable for the "new" product at the pharmacy counter.

245. The "product hop" that Warner Chilcott implemented from Loestrin 24 to Minastrin 24 had no safety, efficacy, or other benefit of any kind for patients. The frivolous modifications that Warner Chilcott made to Loestrin rendered generic Loestrin 24 not A/B-rated to Minastrin 24 and therefore not substitutable for Minastrin 24 at the pharmacy counter. Pharmacists cannot fill a prescription for Minastrin 24 with a generic Loestrin 24. Warner Chilcott made the frivolous modifications to Loestrin 24 for the sole purpose of impairing generic competition beyond the date of expected entry for generic Loestrin 24.

#### 1. Warner Chilcott Made Frivolous Modifications to the Product.

246. On July 9, 2012, Warner Chilcott submitted NDA 203667 for an oral contraceptive consisting of 24 active norethindrone acetate (1mg) / ethinyl estradiol (20 mg) tablets and four inactive ferrous fumarate tablets, which it later sold under the brand name Minastrin 24 Fe. The FDA approved Minastrin 24 for sale on May 8, 2013.

247. Minastrin 24 is Loestrin 24 with two changes: First, Warner Chilcott added spearmint and a sweetener to the inactive pills (only). Second, Warner Chilcott's proposed labeling referred to the pill as chewable and instructed women to chew and then swallow the pill.

248. There is no medical reason for women to take the inactive pills. Women regularly throw out the pack after they have taken the last active pill and do not take the inactive pills. Making the inactive pills more palatable conveys no benefit. In fact, the labeling for Loestrin 24 refers to the inactive tablets as "reminder" pills. It instructs patients to "THROW AWAY" the reminder pills they missed (emphasis in original) if they forget to take one.

249. According to the FDA, the active pills in Loestrin 24 and Minastrin 24 are identical (except for their markings). Warner Chilcott did not do anything to make the Loestrin pills chewable. Nor did Warner Chilcott do anything to make the active Loestrin pills palatable; they added no sweeteners or flavors to the active pills. Warner Chilcott simply changed the label to say that women could chew the pills.

250. Minastrin consists of the same components, composition, doses, and dosing regimen of Loestrin 24 and is indicated for the same use. That is, both drug products are used only for the prevention of pregnancy, and both consist of 24 active white tablets (each containing 1 mg norethindrone acetate and 20 mcg ethinyl estradiol) as well as 4 brown placebo or "reminder" tablets (each containing 75 mg Fe fumarate). According to the FDA, "with the exception of tablet debossing and insignificant manufacturing changes, the proposed drug product [Minastrin 24] is identical to approved Loestrin 24 Fe."

251. Warner Chilcott obtained FDA approval for Minastrin 24 by establishing bioequivalence to Loestrin 24. It conducted no new clinical studies to demonstrate that Minastrin 24 was any more safe or effective than Loestrin 24. Warner Chilcott relied on the previous Phase 3 study of Loestrin 24 tablets for the demonstration of safety and efficacy. Minastrin thus has an identical side effect profile to Loestrin 24. Minastrin also does not result

in any increased rate of patient compliance and is otherwise no better than Loestrin 24 in preventing pregnancy.

252. The notable yet minor difference between the two drug products is simply their method of use. When Minastrin 24 was first introduced, the labeling for the tablets required that patients first chew the tablets before swallowing, compared to Loestrin 24's label, which instructed patients to simply swallow the tablet whole. This change is meaningless (if not undesirable) to patients. But because Minastrin 24 is "chewable," it is considered a different formulation than Loestrin 24 and thus cannot be substituted at pharmacies for generic Loestrin 24.

253. The only purported potential benefit to Minastrin 24 offered by Warner Chilcott to the FDA is that Minastrin 24 "will expand the therapeutic options for women who cannot or will not swallow a whole COC [combined oral contraceptive] tablet but wish to use a COC with an iron supplementation for prevention of pregnancy." This "justification" to reformulate and switch patients is nothing but pretextual nonsense. Loestrin patients by and large were neither in need of nor interested in a birth control pill that they can chew. Indeed, if making pills chewable were a benefit for women, Warner Chilcott could have supplemented or amended its Loestrin 24 NDA to reflect that the product was chewable.

254. But there were no such benefits for women. Individuals who find it difficult to swallow tablets frequently cite size as the reason. Yet Loestrin 24, Minastrin 24, and most other oral birth control products, are merely 6mm in diameter—considered ideal for, and among the smallest of, all oral medications. The size of a tablet is typically not a source of complaint until the tablet becomes greater than 13mm—more than double the size of Loestrin 24. Suffice it say, there was no need to reformulate Loestrin 24 into a chewable tablet based on its size.

255. Complaints about swallowing are also associated more with children and the elderly—the two patient populations who do not take oral contraceptives. Loestrin 24 and Minastrin 24 are not indicated for use before menarche. Nor are they indicated for use by the geriatric patient population.

256. And not only do Loestrin 24 patients not need chewable tablets, they also do want them. Adult patients *prefer* swallowing tablets instead of chewing them at more than a 9 to 1 margin. There is a strong aversion to chewing tablets because doing so creates little fragments that stick to gums or mouth recesses, leaving patients uncertain as to whether they in fact ingested all of the needed medicine.

257. By forcing consumers to switch to an undesirable chewable tablet, Warner Chilcott effectively degraded its product to maintain its monopoly, harming consumers twice over.

**2. Warner Chilcott Cannibalized Loestrin 24 Sales.**

258. Once the FDA approved the reformulated Loestrin 24, Warner Chilcott began marketing the product, labeled as Minastrin 24, in July 2013. This was six months before the delayed entry date for generic Loestrin 24 of January 2014—a delayed entry that Warner Chilcott bought from Watson.

259. As noted in detail above, it is well known in the industry that, where a brand manufacturer successfully converts the market before the generics enter the market, the generics will make few or no sales. Warner Chilcott knew that if it switched the market before generic entry in 2014, the generics would make very few sales because, by that time, Warner Chilcott would have all but eliminated the prescription base. Warner Chilcott would have deprived the generics of their only cost-efficient means of competing for sales.

260. After launching Minastrin 24 in July 2013, Warner Chilcott employed its army of sales force detailers to cannibalize the Loestrin 24 prescriptions, i.e., to aggressively switch them to Minastrin 24. Warner Chilcott bolstered its detailers' efforts by eliminating all promotion of Loestrin 24, such as direct to consumer advertising, free samples, and educational guides. Warner Chilcott switched all of these promotional efforts to Minastrin 24.

261. Data confirm that in the months after the launch of Minastrin 24 in July 2013, nearly 100% of Minastrin 24 sales came from patients who previously had been taking Loestrin 24.

262. Warner Chilcott knew that if it switched the prescription base to Minastrin 24 before January 2014, those prescriptions would not be switched back to Loestrin 24 even after generic versions of that product entered the market. Patients stay on a particular oral contraceptive for long periods of time. And oral contraceptive patients like to stay on a single drug once they find one that works. Patients prefer not to risk unnecessary symptoms or complications by switching drugs.

263. Warner Chilcott's product hop caused enormous concern among women who had previously used Loestrin 24. Many patients were concerned and confused about why they now had to chew a product that they had previously swallowed. Having caused all the concern and confusion in order to impair generic competition, after generics finally entered the market Warner Chilcott eventually changed the label for Minastrin 24 to say that women could chew *or swallow* the pills.

### 3. Warner Chilcott Forced Patients to Switch by Withdrawing Loestrin 24 from the Market.

264. In order to overcome doctors' and patients' reluctance to switch oral contraceptives, in August 2013—just after Warner Chilcott successfully extracted a delayed

entry date from Mylan—Warner Chilcott altogether withdrew Loestrin 24 from the market. Warner Chilcott stopped manufacturing Loestrin 24 and it became no longer available in the marketplace.

265. Warner Chilcott did not give any advanced warning that it was discontinuing Loestrin 24. It offered no safety or efficacy concerns for withdrawing Loestrin 24 from the market.

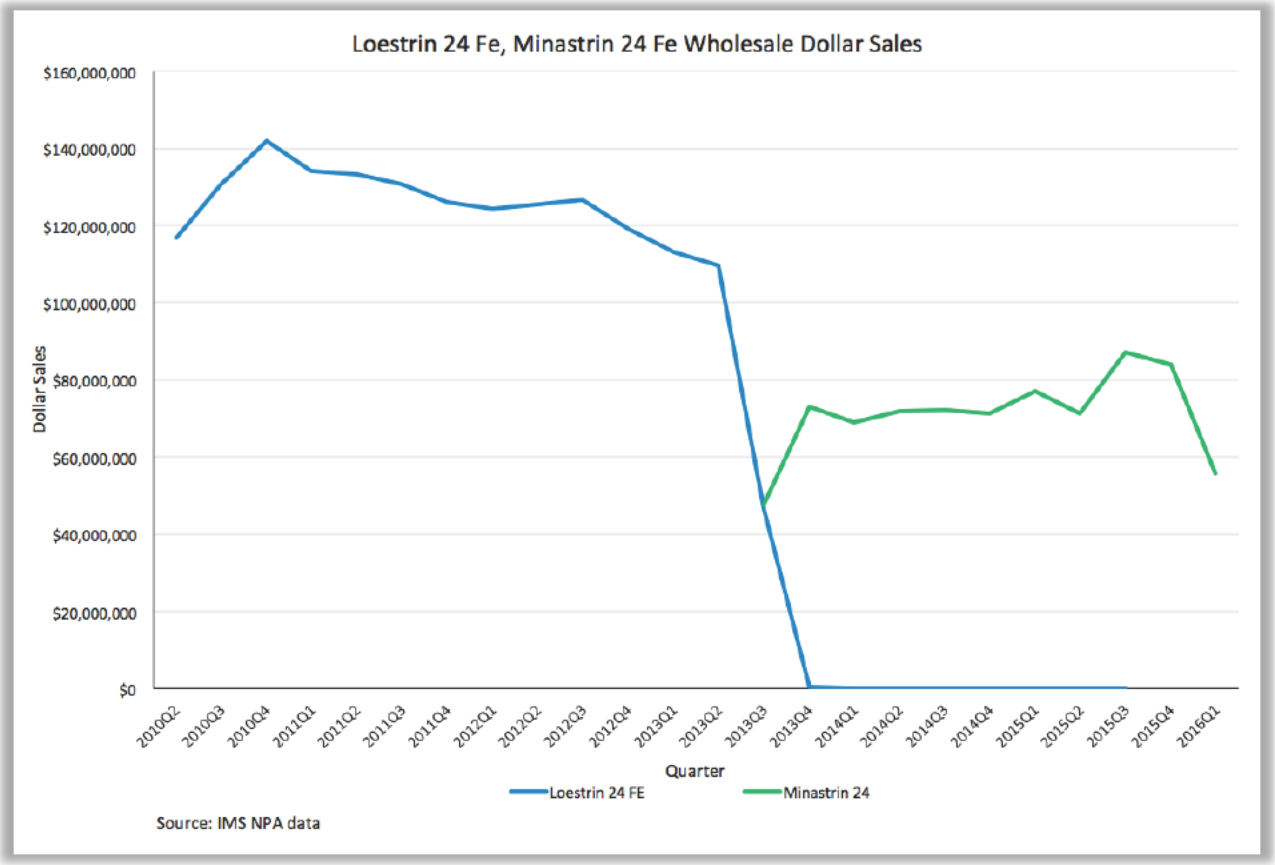
266. When it suddenly removed Loestrin 24 from the market, patients seeking to refill their Loestrin 24 prescriptions could not do so. Instead, Warner Chilcott insisted to pharmacies, doctors, and patients that Minastrin 24 is the replacement to which patients should switch. This forced patients who had become stabilized on the 24-day regimen and who were tolerating it well to switch to Minastrin 24.

#### 4. Warner Chilcott's Sole Motive in Switching the Market Was to Impair Generic Competition.

267. The exclusionary motive and effect of Warner Chilcott's product hop is confirmed by the fact that the hop made economic sense for Warner Chilcott only because it had the effect of impairing generic competition. Warner Chilcott's decision to incur the extra costs (and suffer the revenue losses) associated with the change in dosage form from Loestrin 24 to Minastrin 24 was economically rational only because the change had the exclusionary effect of impairing generic competition. But for the impact on generic competition, Warner Chilcott would not have invested the resources necessary to reformulate and cannibalize Loestrin 24 because doing so would have been economically irrational.

268. Warner Chilcott experienced a loss of sales due to the product hop from Loestrin 24 to Minastrin 24. Warner Chilcott knew when it was planning the product hop that its combined sales of Loestrin 24 and Minastrin 24 would be far less than its sales of Loestrin 24

before the hop. This chart of Warner Chilcott's dollar sales shows that Warner Chilcott's projections were correct:




269. Warner Chilcott incurred very substantial costs in order to garner these reduced sales. Warner Chilcott spent significant sums in order to develop Minastrin 24, obtain a patent that purportedly protected it, gain FDA approval, and promote the product.

270. If the product hop did not have the effect of impairing generic competition, the hop would have been a money-losing proposition for Warner Chilcott. The product hop made economic sense for Warner Chilcott solely because the hop did have the effect of impairing generic competition. Warner Chilcott's investments in reformulating and cannibalizing the sales

of Loestrin 24 were not investments in improving products and helping patients; they were investments in impairing competition.

**5. Warner Chilcott's Delay in Marketing Minastrin 24 Confirms the Purpose and Effect of Impairing Generic Competition.**

271. If Minastrin 24 were a valuable improvement over Loestrin 24, and not merely a means of impairing generic competition, Warner Chilcott would have introduced Minastrin 24 as early as possible. A valuable improvement would have helped Warner Chilcott compete against other branded oral contraceptives in non-price dimensions. Instead, Warner Chilcott chose to delay marketing Minastrin for more than four years.

272. Warner Chilcott has substantial experience in developing chewable versions of oral contraceptive tablets. Before reformulating Loestrin 24, Warner Chilcott had developed and marketed chewable versions of its oral contraceptive tablets. On November 14, 2003, Warner Chilcott obtained FDA approval for Ovcon 35 chewable tablets (later renamed Femcon). On April 25, 2011, Warner Chilcott obtained approval for Generess chewable tablets. And just two months after obtaining approval for Minastrin, Warner Chilcott obtained FDA approval for Lo Minastrin—the chewable counterpart to Warner Chilcott's Lo Loestrin that Warner Chilcott has refrained from launching. And Warner Chilcott knew that it could obtain a three-year marketing exclusivity for Minastrin 24 by submitting a study showing that it had no worse a safety profile than Loestrin 24. 21 U.S.C. § 355(j)(5)(F)(iii). For every chewable tablet formulation, Warner Chilcott knew that the FDA would condition approval on it submitting an oral irritation study—a standard request by the FDA that required Warner Chilcott to examine about 50 patients' mouths for signs of irritation after chewing a tablet—that enabled Warner Chilcott to later claim the three-year exclusivity.

273. Warner Chilcott first submitted its NDA (022365) for Minastrin on May 20, 2008. On January 12, 2009, just months away from expected FDA approval of the reformulation, Warner Chilcott withdrew its request for FDA approval. The FDA noted that Warner Chilcott withdrew the request for approval "for business reasons."

274. The "business reason" was that three days earlier, on January 9, 2009, Warner Chilcott had bought from Watson its agreement to delay entering the market with generic Loestrin 24 until January 2014. Warner Chilcott's sole purpose in reformulating the product was to impair generic competition. So having bought a delay in generic competition, Warner Chilcott no longer had an immediate need to reformulate the product.

275. Warner Chilcott re-submitted the same NDA on September 12, 2010. Warner Chilcott then withdrew it a second time on November 15, 2010—a month after it bought Lupin's agreement to delay marketing its generic Loestrin 24 until July 2014. Again, having bought a delay in generic competition, Warner Chilcott no longer had an immediate need to reformulate the product.

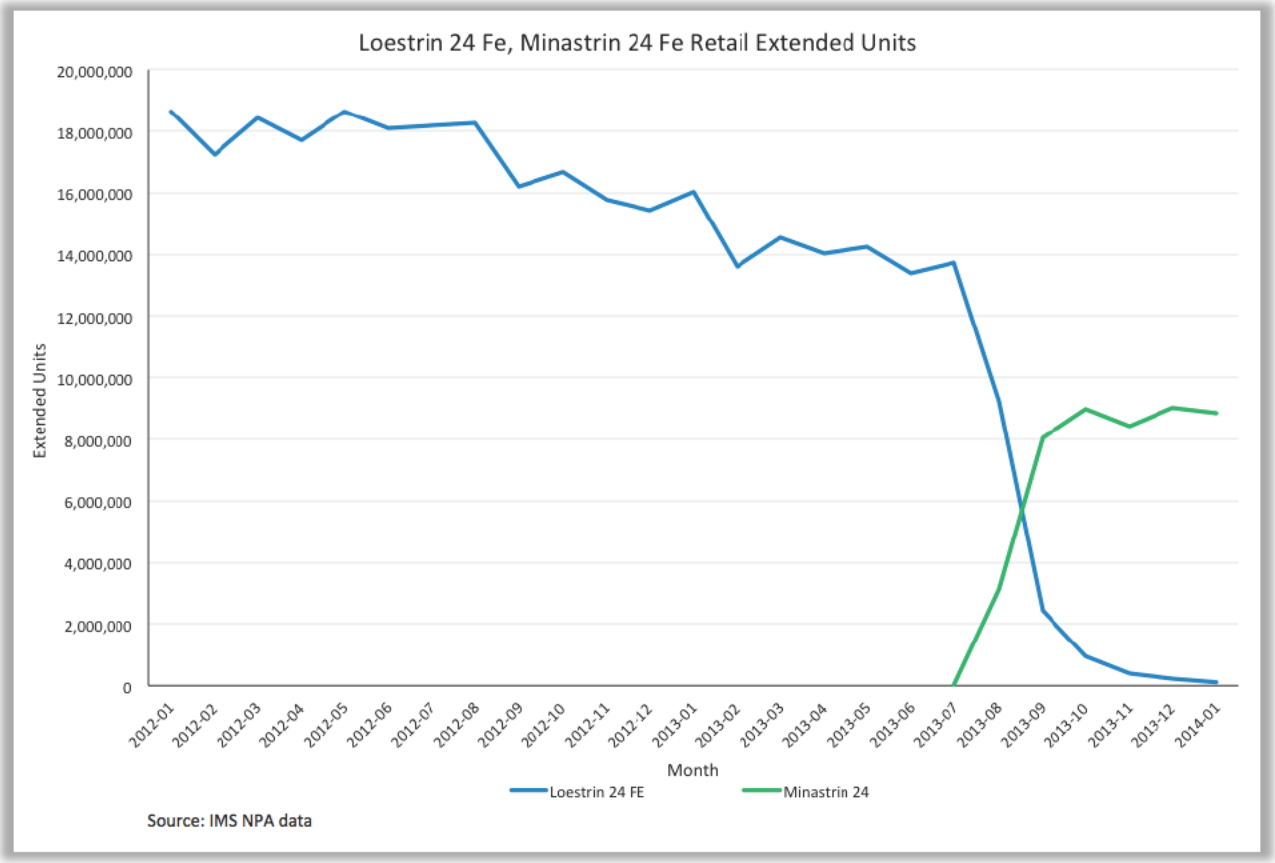
276. Warner Chilcott re-submitted the Minastrin NDA on July 9, 2012 (this time under NDA 203667) and pursued it to completion only when the delays that Warner Chilcott bought from Watson and Lupin were finally coming to an end. Mindful of the need to convert the market from Loestrin 24 to Minastrin 24 before generic Loestrin 24 entered the market, Warner Chilcott obtained FDA approval for the latter on May 8, 2013, with exclusivity extending until May 8, 2016. Warner Chilcott then implemented the product hop beginning in July 2013—in just enough time to convert the market before the Watson generic was scheduled to enter in January 2014.

277. The one patent that covers Minastrin is U.S. Patent No. 6'667'050 (the "'050 patent"). The '050 patent, which claims a chewable oral contraceptive formulation, also covers Generess. In its litigation relating to its Generess ANDA, Lupin obtained a favorable judgment on April 29, 2014, invalidating as obvious the asserted claims in the '050 patent. On June 6, 2014, Warner Chilcott again filed a complaint asserting the '050 patent against Lupin (and later Amneal and Mylan), this time relating to Lupin's first-to-file ANDA for Minastrin. Sometime around April 2015, Warner Chilcott entered into an agreement with Lupin pursuant to which they jointly dismissed the Generess appeal, filed a motion to vacate the district court's judgment and (sealed) opinion invalidating the '050 patent (which was granted), and dismissed the Minastrin patent litigation.

**6. Warner Chilcott's Product Hop Substantially Impaired Generic Competition.**

278. Warner Chilcott's product hop and withdrawal of Loestrin 24 from the market was enormously successful for Warner Chilcott. Had Warner Chilcott not converted the market from Loestrin 24 to Minastrin 24, 100% of the prescriptions written for Warner Chilcott's oral contraceptive comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets would have been A/B-rated to and subject to automatic substitution with generic Loestrin 24.

279. Instead, Warner Chilcott successfully converted all Loestrin 24 prescriptions to Minastrin 24 before Watson's generic entered in January 2014. As this chart demonstrates, Warner Chilcott's anticompetitive conduct ensured that there were essentially *no* sales of branded Loestrin 24 by January 2014:




280. To overcome the price disconnect in pharmaceutical markets, Congress and every State promote the distribution of generic drugs through automatic substitution at the pharmacy counter. Such substitution is generic manufacturers' cost-efficient means of competing. Warner Chilcott's product hop and withdrawal of Loestrin 24 from the market altogether deprived generic manufacturers of their cost-efficient means of competing, and altogether deprived purchasers and consumers of the benefits of that competition.

## VI. ANTICOMPETITIVE EFFECTS OF THE SCHEME

281. Warner Chilcott's scheme and payments to suppress generic competition to Loestrin 24 have delayed and substantially diminished the sale of generic Loestrin 24. By delaying the onset of generic competition and decimating the prescription base, Defendants

deprived would-be generic manufacturers of the most efficient means of distribution under the governing statutory and regulatory regime.

282. Warner Chilcott's overarching anticompetitive scheme, and the Generic Defendants' participation in it, delayed and substantially diminished the sale of generic Loestrin 24 in the United States, and unlawfully enabled Warner Chilcott to sell Loestrin 24 drugs at artificially inflated prices. But for Defendants' illegal conduct, generic manufacturers would have been able to enter the market unimpeded and compete on the merits against Loestrin 24. Generic competitors would also have been able to compete earlier, as early as September 2009, and additional generic competitors would have entered the market thereafter. Defendants' conduct unlawfully prevented purchasers of Loestrin 24 drugs from obtaining the benefits of unimpaired generic competition.

283. Defendants' scheme and unlawful payments harmed Plaintiffs and the End-Payor Class by depriving them of: (1) a market in which manufacturers and distributors of generic drugs make their decisions about challenging patents and entering markets free from the influence of unlawful payments; and (2) the most cost efficient means of distribution. Contrary to the purpose of the Hatch-Waxman Amendments, the anticompetitive scheme and payments have enabled Defendants to: (1) delay the entry of less expensive generic versions of Loestrin 24 in the United States; (2) fix, raise, maintain or stabilize the price of Loestrin 24 drugs; (3) allocate 100% of the U.S. market for Loestrin 24 drugs to Warner Chilcott.

284. But for the anticompetitive scheme: (1) Watson would have begun selling AB-rated generic versions of Loestrin 24 on or shortly after receiving final FDA approval of its generic Loestrin 24 ANDA on September 1, 2009; and (2) an increasingly competitive market for Loestrin 24 drugs would have emerged; and (3) Warner Chilcott would not have developed

or marketed Lo Loestrin or Minastrin 24 and switched a substantial portion of sales to those products and/or generic Loestrin 24 would have entered the market before Lo Loestrin and Minastrin 24, and Warner Chilcott would have been able to switch few prescriptions to those products.

285. Defendants' unlawful conduct has delayed and diminished the sale of generic Loestrin 24 in the United States, and unlawfully enabled Warner Chilcott to sell Loestrin 24 drugs at artificially inflated, supracompetitive prices. But for Defendants' illegal conduct, generic competition to Loestrin 24 would have occurred as early as September 2009, Warner Chilcott or its designee would have entered the market with an authorized generic version of Loestrin 24 at or about the same time, and 100% of the prescriptions for Loestrin 24 drugs would have been available for automatic generic substitution.

286. As a consequence, Plaintiffs and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

## VII. CLASS ACTION ALLEGATIONS

287. Plaintiffs bring this action on behalf of themselves and, under Fed. R. Civ. P. 23(a), 23(b)(2), and (b)(3), as representative of an End-Payor Class defined as follows:

> All persons or entities in the United States and its territories who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Loestrin 24 Fe and/or its AB-rated generic equivalents in any form, and/or Minastrin 24 Fe and/or its AB-rated generic equivalents in any form, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the "Class" or the "End-Payor Class"), other than for resale, during the period September 1, 2009 through and until the anticompetitive effects of Defendants' unlawful conduct cease (the "Class Period"). For purposes of the Class definition, persons or entities "purchased" Loestrin 24 Fe, Minastrin 24 Fe, or their generic equivalents if they indirectly purchased, paid and/or reimbursed for some or all of the purchase

price.

288. The following persons or entities are excluded from the proposed End-Payor Class:

a. Defendants and their officers, directors, management, employees, subsidiaries, or affiliates;

b. All federal or state governmental entities, excluding cities, towns or municipalities with self-funded prescription drug plans;

c. All persons or entities who purchased Loestrin 24 Fe or its AB-rated generic equivalent, and/or Minastrin 24 Fe or its AB-rated generic equivalent, for purposes of resale or directly from Defendants or their affiliates;

d. Fully insured health plans (i.e., Plans that purchased insurance from another third-party payor covering 100% of the Plan's reimbursement obligations to its members);

e. Any "flat co-pay" consumers whose purchases were paid in part by a third party payor and whose co-payment was the same regardless of the retail purchase price;

f. Any "brand loyalist" consumers or third-party payors who purchased Loestrin 24 Fe and who did not purchase any AB-rated generic equivalent after such generics became available; and

g. The judges in this case and any members of their immediate families.

289. Members of the End-Payor Class are so numerous that joinder is impracticable. Plaintiffs believe that the Class includes hundreds of thousands, if not millions, of consumers, and thousands of third-party payors.

290. Plaintiffs' claims are typical of those of the members of the End-Payor Class. Plaintiffs and all members of the End-Payor Class were damaged by the same wrongful conduct of Defendants, i.e., they paid artificially inflated prices for Loestrin 24 drugs and were deprived of the benefits of earlier and more robust competition from cheaper generic versions of Loestrin 24 as a result of Defendants' wrongful conduct.

291. Plaintiffs will fairly and adequately protect and represent the interests of the End-Payor Class. The interests of the Plaintiffs are coincident with, and not antagonistic to, those of the End-Payor Class.

292. Plaintiffs are represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular experience in class action antitrust litigation involving pharmaceutical products.

293. Questions of law and fact common to the members of the End-Payor Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire End-Payor Class, thereby making overcharge damages with respect to the End-Payor Class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

294. Questions of law and fact common to the End-Payor Class include, but are not limited to:

a. whether Defendants conspired to suppress generic competition to Loestrin 24;

b. whether Defendants Warner Chilcott and Watson entered into an unlawful agreement in restraint of trade;

c. whether, pursuant to the agreement, Watson agreed to delay its entry into the market with generic Loestrin 24;

d. whether, pursuant to the agreement, Warner Chilcott compensated Watson;

e. whether Warner Chilcott's compensation to Watson was for a purpose other than delayed entry of generic Loestrin 24;

f. whether Warner Chilcott's compensation to Watson was necessary to yield some procompetitive benefit that is cognizable and non-pretextual;

g. whether the agreement is illegal under the rule of reason;

h. whether Defendants Warner Chilcott and Lupin entered into an unlawful agreement in restraint of trade;

i. whether, pursuant to the agreement, Lupin agreed to delay its entry into the market with generic Loestrin 24;

j. whether, pursuant to the agreement, Warner Chilcott compensated Lupin;

k. whether Warner Chilcott's compensation to Lupin was for a purpose other than delayed entry of generic Loestrin 24;

l. whether Warner Chilcott's compensation to Lupin was necessary to yield some procompetitive benefit that is cognizable and non-pretextual;

m. whether the agreement is illegal under the rule of reason;

n. whether, absent the delay caused by Defendants' unlawful payments, Warner Chilcott would have launched and marketed Lo Loestrin;

o. whether Warner Chilcott introduced, priced, and marketed Minastrin 24 in order to impair competition from generic Loestrin 24;

p. whether the law requires definition of a relevant market when direct proof of market power is available and, if so, the definition of the relevant market;

q. whether the activities of Defendants as alleged herein have substantially affected interstate commerce;

r. whether, and to what extent, Defendants' conduct caused antitrust injury (i.e., overcharges) to Plaintiffs and the members of the Class; and

s. the quantum of aggregate overcharge damages to the Class.

295. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

296. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

## VIII. INTERSTATE AND INTRASTATE COMMERCE

297. At all material times, Warner Chilcott manufactured, marketed, promoted, distributed, and sold substantial amounts of Loestrin 24 and Minastrin 24 in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

298. At all material times, Defendants transmitted funds, as well as contracts, invoices and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Loestrin 24 and Minastrin 24 and/or their AB-rated bioequivalents.

299. In furtherance of their efforts to restrain competition in the market for Loestrin 24 drugs, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. Defendants' activities were within the flow of and have substantially affected interstate commerce.

300. Defendants' anticompetitive conduct has substantial intrastate effects in that, inter alia, retailers within each state were impaired in offering less expensive generic Loestrin 24 to end-payors inside each respective state. The impairment of competition from generic Loestrin 24 directly impacts and disrupts commerce for end-payors within each state.

## IX. MARKET POWER AND MARKET DEFINITION

301. At all relevant times Warner Chilcott had monopoly power in the market for Loestrin 24 drugs and narrower markets therein, because it had the power to raise or maintain the price of Loestrin 24 drugs at supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable.

302. Warner Chilcott had the ability to control the prices of Loestrin 24 drugs and exclude relevant competitors. Direct evidence demonstrates that: (a) generic versions of each drug would have entered the market at substantial discounts to the brands but for the defendants' anticompetitive conduct; (b) the gross margin on each drug was at all times at least 60%; and (c) the defendants never lowered the price of the drugs to the competitive level in response to the pricing of other branded or generic drugs.

303. To the extent that Plaintiffs are required to prove monopoly power by defining a relevant product market, Plaintiffs allege that the relevant product market is the market for Loestrin 24 drugs and narrower markets therein.

304. A small but significant, non-transitory price increase in the price of Loestrin 24 drugs did not cause a significant loss of sales. At competitive prices, Loestrin 24 drugs do not exhibit significant, positive, cross-elasticity of demand with respect to price with any other oral contraceptive other than AB-rated generic versions of those Loestrin 24 drugs.

305. Warner Chilcott needed to control only Loestrin 24 drugs and their AB-rated generic equivalents, and no other products, in order to maintain the price of the products profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Loestrin 24 drugs would render the defendants unable to profitably maintain supracompetitive prices for those products.

306. Warner Chilcott sold branded Loestrin 24 drugs in excess of marginal costs, and in excess of the competitive price, and enjoyed unusually high profit margins.

307. The United States and its territories constitute the relevant geographic market.

308. At all relevant times, Warner Chilcott enjoyed high barriers to entry with respect to the above-defined relevant market due to patent protection, the high cost of entry and

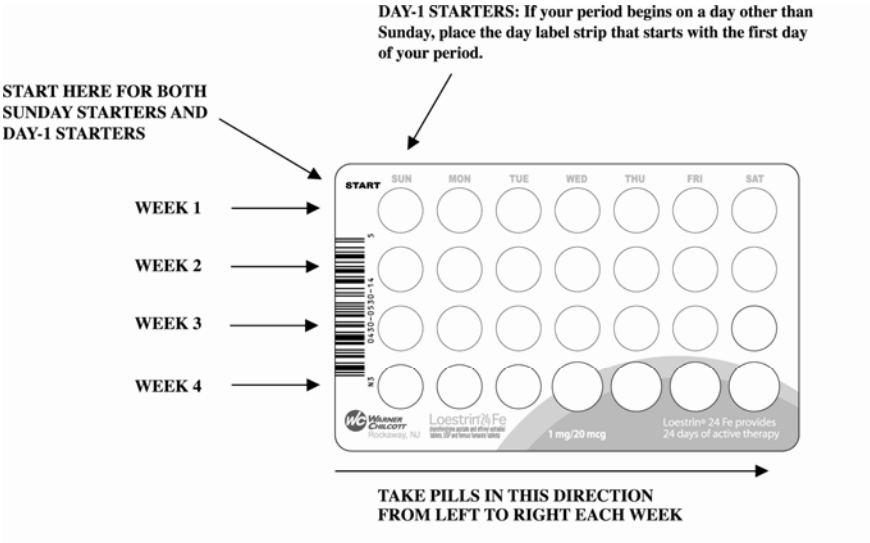
expansion, expenditures in marketing and physician detailing, and AB-rated generic substitution laws.

309. At all relevant times, Warner Chilcott's market share in the relevant market was 100%.

310. Loestrin 24 and Minastrin 24 also are not reasonably interchangeable with any products other than AB-rated generic versions of Loestrin 24 Drugs because Loestrin 24 and Minastrin 24 have different attributes significantly differentiating them from other oral contraceptives and making them unique. The FDA does not consider Loestrin 24 drugs and other oral contraceptives interchangeable, and there is variation in the dosage of the active ingredients. Oral contraceptives have different chemical compounds and formulations, such as varying amounts of progestin.

311. Oral contraceptive pills are dispensed in packs, where each pack contains the right number of pills to last for one cycle (28 days). Each pack contains between 21 and 28 pills. Each pill is labeled with either a day of the week (M, T, W, etc.) or the day of the cycle (Day 1, Day 2, Day 3, etc.) when it should be taken.

312. 




313. Some formulations of oral contraceptives have higher failure rates in certain classes of women, and they differ widely in their safety and side-effect profiles. For example, oral contraceptives differ in the endometrial, progestational, androgenic and estrogenic activity. The differing efficacy, safety and side effect profiles of different oral contraceptives play a critical role in doctors' selection of the most appropriate oral contraceptive for a particular patient and a woman's decision to continue taking an oral contraceptive she has found to work well.

314 Price does not drive prescriptions for oral contraceptives. The pharmaceutical marketplace is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Loestrin 24 drugs, to patients without a prescription written by a doctor. This prohibition introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

315. Warner Chilcott and other brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and aggressively (and sometimes illegally) persuade them to prescribe the manufacturer's products.[14] These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

316. Thus, unlike many consumer products where consumers are provided with a choice of functionally similar products at the point of sale and make purchasing decisions primarily based on price, the prescribing decision for prescription drugs, such as oral contraceptives, is made by the physician, not female consumers of these products. Additionally, once the physician and patient find a product that is well-tolerated, it is very unlikely that the patient will switch to a different oral contraceptive based on variations of price of 10% or less.

317. Doctors generally select an oral contraceptive for their patients based on the clinical and pharmacological attributes of the drug and the relevant characteristics of the patient, rather than on the basis of price. For clinical reasons, among others, physicians and patients prefer Loestrin 24 drugs to other products designed to prevent pregnancy. Due to, among other reasons, their use and varying ability to prevent pregnancy while causing shorter, lighter periods,

[14] In fact, Warner Chilcott admittedly instructed its sales representatives to use illegal tactics to increase and maintain its market share. In October 2015, Warner Chilcott pleaded guilty to criminal and civil charges of unlawfully marketing several of its drugs, including Loestrin 24. Among other things, Warner Chilcott violated the federal anti-kickback statute by providing inducements to physicians to prescribe Warner Chilcott's drugs. Warner Chilcott agreed to pay $102.06 million to the federal government and certain states, resolving claims that its actions caused false claims to be submitted to government health care programs. Warner Chilcott also agreed to pay a criminal fine of $22.94 million.

Loestrin 24 drugs are significantly differentiated from all products other than AB-rated generic versions of Loestrin 24 drugs.

318. The existence of other products designed to prevent pregnancy has not significantly constrained Warner Chilcott's pricing of Loestrin 24 drugs.

319. Warner Chilcott needed to control only Loestrin 24 drugs, and no other products, in order to maintain the price of Loestrin 24 drugs profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Loestrin 24 drugs would render Warner Chilcott unable to profitably maintain its current prices of Loestrin 24 drugs without losing substantial sales.

320. Despite the availability of other oral contraceptive products, including lower priced generics that are not AB-rated to Loestrin 24 drugs, sales of Loestrin 24 increased from 2008 to 2011, and the price of Loestrin 24 rose each year. This is in stark contrast to what would have occurred if an AB-rated generic version of Loestrin 24 had come to market. For example, when an AB-rated generic version of Yaz-28, an oral contraceptive sold by Bayer Healthcare, became available in 2010, sales of branded Yaz-28 dropped from a reported $781 million in 2009, to $150 million in 2011. The generic version of Yaz-28 was not AB-rated, however, to Loestrin 24 and, thus, not surprisingly, while sales of branded Yaz-28 plunged from 2009 to 2011, sales of branded Loestrin 24 *increased* between 2009 and 2011.

## X. MARKET EFFECTS AND DAMAGES TO THE CLASS

321. But for the anticompetitive conduct alleged above, Watson would have entered the market with its generic Loestrin 24 as early as September 1, 2009, the date its ANDA 78-267 received final FDA approval. Warner Chilcott would have begun marketing an authorized

generic version of Loestrin 24 at that same time. Lupin and other generic manufacturers would have entered the market with additional generic version of Loestrin 24 thereafter.

322. Defendants' anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Loestrin 24 drugs from generic competition.

323. Watson and Lupin have extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products, manufacturing commercial launch quantities adequate to meet market demand, and, where appropriate, paying and receiving consideration for selective waiver and/or relinquishment of 180-day first-to-file marketing exclusivities.

324. Defendants' anticompetitive conduct, which impaired competition from generic versions of Loestrin 24, has caused Plaintiffs and the Class to pay more than they would have paid for Loestrin 24 drugs absent Defendants' illegal conduct.

325. Typically, generic versions of brand drugs are initially priced significantly below the corresponding brand drug to which they are AB-rated. As a result, upon generic entry, end-payors rapidly substitute generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further due to competition among the generic manufacturers, and, correspondingly, the brand drug loses even more of its market share to the generic versions of the drug. This price competition enables all purchasers of the drug to: (a) purchase generic versions of a drug at substantially lower prices, and/or (b) purchase the brand drug at a reduced price. Consequently, brand manufacturers have a keen financial interest in delaying and impairing generic

competition, and purchasers experience substantial cost inflation from that delay and impairment.

326. But for Defendants' anticompetitive conduct, end-payors, such as Plaintiffs and members of the Class, would have paid less for Loestrin 24 drugs by: (a) substituting purchases of less-expensive AB-rated generic Loestrin 24 for their purchases of more-expensive branded Loestrin 24; (b) receiving discounts on their remaining branded Loestrin 24 purchases; and (c) purchasing generic Loestrin 24 at lower prices sooner.

327. Moreover, due to Defendants' anticompetitive conduct, other generic manufacturers were discouraged from and/or delayed in (a) developing generic versions of Loestrin 24, and/or (b) challenging the validity or infringement of the '394 patent in court.

328. During the Class Period, Plaintiffs and other members of the Class purchased substantial amounts of Loestrin 24 drugs. As a result of Defendants' illegal conduct as alleged herein, Plaintiffs and other members of the Class were compelled to pay, and did pay, artificially inflated prices for Loestrin 24 drugs. Plaintiffs and the other Class members paid prices for Loestrin 24 drugs that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Class members were deprived of the opportunity to purchase lower-priced generic Loestrin 24 instead of expensive brand Loestrin 24 and/or brand Minastrin 24; and (2) Class members paid artificially inflated prices for Loestrin 24 drugs.

329. As a consequence, Plaintiffs and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

330. Thus, Defendants' unlawful conduct deprived Plaintiffs and the Class of the benefits of competition that the antitrust laws were designed to ensure.

## XI. ANTITRUST IMPACT

331. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of brand Loestrin 24 and/or Minastrin 24 indirectly from Defendants and/or purchased substantial amounts of AB-rated Loestrin 24 bioequivalent generic indirectly from Defendants or others. As a result of Defendants' illegal conduct, members of the End-Payor Class were compelled to pay, and did pay, artificially inflated price for their Loestrin 24 drugs requirements. Those prices were substantially greater than the prices that members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of brand Loestrin 24 and brand Minastrin 24 was artificially inflated by Defendants' illegal conduct, (2) Class members were deprived of the opportunity to purchase lower-priced generic versions of Loestrin 24, and/or (3) the price of AB-rated Loestrin 24 generic was artificially inflated by Defendants' illegal conduct.

332. As a consequence, Plaintiffs and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

333. Overcharges at a higher level of distribution generally result in higher prices at every level below.

334. Wholesalers and retailers passed on the inflated prices of Loestrin 24 drugs to the End-Payors defined herein.

335. Defendants' anticompetitive conduct enabled them to indirectly charge consumers and third-party payors prices in excess of what Defendants otherwise would have been able to charge absent Defendants' anticompetitive conduct.

336. The prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

337. The inflated prices the End-Payor Class paid are traceable to, and the foreseeable result of, the overcharges by Defendants.

## XII. CLAIMS FOR RELIEF

### FIRST CLAIM FOR RELIEF

**Monopolization and Monopolistic Scheme Under State Law**
**(Against Warner Chilcott)**

338. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

339. At all relevant times, Warner Chilcott possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Warner Chilcott possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

340. Through the overarching anticompetitive scheme, as alleged extensively above, Warner Chilcott willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiffs and the Class thereby.

341. It was Warner Chilcott's conscious objective to further its dominance in the relevant market by and through the overarching anticompetitive scheme.

342. As stated more fully above, Defendants knowingly, willfully, and wrongfully maintained their monopoly power and harmed competition by:

a. listing a patent they knew to be invalid and/or unenforceable in the Orange Book;

b. asserting that patent in sham lawsuits against generic Loestrin 24 manufacturers to delay generic competition;

c. paying competitor Watson to delay marketing its generic Loestrin 24;

d. deterring other generic manufacturers from marketing generic Loestrin 24 before Watson entered the market through use of an anticompetitive acceleration clause;

e. paying competitor Lupin to delay marketing its generic Loestrin 24;

f. switching the market from Loestrin 24 to Minastrin 24—a nearly identical product with no benefits or improvements—during that purchased delay; and

g. withdrawing Loestrin 24 from the market in order to coerce doctors and patients to switch to Minastrin 24.

343. To the extent Warner Chilcott is permitted to assert one, there is and was no cognizable, non-pretextual procompetitive justification for Warner Chilcott's actions comprising the anticompetitive scheme that outweigh the scheme's harmful effects. Even if there were some conceivable such justification that Warner Chilcott were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

344. As a direct and proximate result of Warner Chilcott's illegal and monopolistic conduct, as alleged herein, Plaintiffs and the Class were injured.

345. By engaging in the foregoing conduct, Warner Chilcott has intentionally and wrongfully maintained monopoly power in the relevant market in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Loestrin 24 in Arizona by members of the Class.

b. Cal. Bus. & Prof Code §§ 17200, *et seq.*, and California common law with respect to purchases of Loestrin 24 in California by members of the Class.

c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Loestrin 24 in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Loestrin 24 in Florida by members of the Class.

e. Hawaii Rev. Stat. 480-1, *et seq.*, with respect to purchases of Loestrin 24 in Florida by members of the Class.

f. Iowa Code §§ 553.5 *et seq.*, with respect to purchases of Loestrin 24 in Iowa by members of the Class.

g. Kansas Stat. Ann. § 50-161 (b) *et seq.*, with respect to purchases of Loestrin 24 in Kansas by members of the Class.

h. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Loestrin 24 in Maine by members of the Class.

i. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases of Loestrin 24 in Massachusetts by members of the Class.

j. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of Loestrin 24 in Michigan by members of the Class.

k. Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Loestrin 24 in Minnesota by members of the Class.

l. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Loestrin 24 in Mississippi by members of the Class.

m. Mo. Rev. Stat. §§ 416.011, *et seq.*, with respect to purchase in Missouri by members of the Class.

n. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Loestrin 24 in Nebraska by members of the Class.

o. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Loestrin 24 in Nevada by members of the Class.

p. N.H. Rev. Stat. Ann. §§ 356.11, with respect to purchases of Loestrin 24 in New Hampshire by members of the Class.

q. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Loestrin 24 in New Mexico by members of the Class.

r. N.Y. Gen. Bus. Law §340 ("The Donnelly Act"), with respect to purchases of Loestrin 24 in New Mexico by members of the Class

s. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Loestrin 24 in North Carolina by members of the Class.

t. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of Loestrin 24 in North Dakota by members of the Class.

u. 10 L.P.R.A. §§ 260, *et seq.*, with respect to purchases of Loestrin 24 in Puerto Rico by members of the Class.

v. R.I. Gen. Laws §§ 6-36-5 *et seq.,* with respect to purchases in Rhode Island by members of the Class.

w. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of Loestrin 24 in South Dakota by members of the Class.

x. Tenn. Code Ann §§ 47-25-101, *et seq.,* with respect to purchases of Loestrin 24 in Tennessee by members of the Class.

y. Utah code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Loestrin 24 in Utah by members of the Class.

z. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Loestrin 24 in Vermont by members of the Class.

aa. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Loestrin 24 in West Virginia by members of the Class.

bb. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Loestrin 24 in Wisconsin by members of the Class.

## SECOND CLAIM FOR RELIEF

**Conspiracy and Combination in Restraint of Trade Under State Law (Against Warner Chilcott and Watson)**

346. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

347. The Exclusion Payment Agreement between Warner Chilcott and Watson involves: (a) a payment from Warner Chilcott to Watson; and (b) an agreement by Watson to delay marketing its generic Loestrin 24 until January 22, 2014. The payments from Warner Chilcott to Watson under the Agreement was the quid pro quo for Watson's agreement to delay marketing its generic versions of Loestrin 24 over four years. Absent the payments, Watson would not have agreed to delay marketing its generic versions of Loestrin 24 until January 22, 2014.

348. The purpose and effect of the payments flowing from Warner Chilcott to Watson under the agreement was to delay generic competition to Loestrin 24 and there is and was no legitimate, non-pretextual, precompetitive business justification for the payment that outweighs its harmful effect. Even if there were some such conceivable justification, the payment was not necessary to achieve such a purpose.

349. The purpose and effect of the unlawful Exclusion Payment Agreement between Warner Chilcott and Watson was to allocate 100% of the market for Loestrin 24 and its generic equivalents in the United States to Warner Chilcott; delay the sales of generic Loestrin 24 products for over four years; and fix the price at which consumers and other End-Payor Plaintiffs would pay for Loestrin 24 and its generic equivalents at the higher, branded price.

350. The Exclusion Payment Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

351. As a direct and proximate result of Defendants' unlawful restraint of trade, Plaintiffs and members of the Class paid artificially inflated prices for Loestrin 24 and its generic equivalents as described herein, and were harmed as a result.

352. By engaging in the foregoing conduct, Defendants have violated the following state laws:

a. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Arizona Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases of Loestrin 24 in Arizona by members of the Class.

b. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Cal. Bus. Code §§ 16700, *et seq.*, and Code §§ 17200, *et seq.*, with respect to purchases of Loestrin 24 in California by members of the Class.

c. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of D.C. Code Ann. §§ 28-45031, *et seq.*, with respect to purchases of Loestrin 24 in the District of Columbia by members of the Class.

d. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Fla. Stat. §§ 501. Part II, *et seq.*, with respect to purchases of Loestrin 24 in Florida by members of the Class, and this conduct constitutes a predicate act under the Florida Deceptive Practices Act.

e. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Loestrin 24 in Illinois by members of the Class.

f. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Iowa Code §§ 553.5 *et seq.*, with respect to purchases of Loestrin 24 in Iowa by members of the Class.

g. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Loestrin 24 in Kansas by members of the Class.

h. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases of Loestrin 24 in Maine by members of the Class.

i. Defendant have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Mass. Ann. Laws ch. 93, *et seq.*, with respect to purchases of Loestrin 24 in Massachusetts by members of the Class.

j. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to purchases of Loestrin 24 in Michigan by members of the Class.

k. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Minn. Stat. §§ 325D.52, *et seq.*, with respect to purchases of Loestrin 24 Minnesota by members of the Class.

l. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases of Loestrin 24 in Mississippi by members of the Class.

m. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of Loestrin 24 in Nebraska by members of the Class.

n. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Nev. Rev. Stat. Ann. § 598A, *et*

*seq.*, with respect to purchases of Loestrin 24 in Nevada by members of the Class, in that thousands of sales of Loestrin 24 took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct.

o. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of Loestrin 24 in New Mexico by members of the Class.

p. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of New York General Business Law § 340, *et seq.*, with respect to purchases of Loestrin 24 in New York by members of the Class.

q. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Loestrin 24 in North Carolina by members of the Class.

r. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of N.D. Cent. Code § 51-08.1-01, *et seq.*, with respect to purchases of Loestrin 24 in North Dakota by members of the Class.

s. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Loestrin 24 in Oregon by members of the Class.

t. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of 10 L.P.R.A. §§ 260, *et seq* with respect to purchases of Loestrin 24 in Puerto Rico by members of the Class.

u. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of R.I. Gen. Laws §§ 6-36-5, *et seq.* with respect to purchases of Loestrin 24 in Rhode Island by members of the Class.

v. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of S.D. Codified Laws Ann. § 37-1, *et seq.*, with respect to purchases of Loestrin 24 in South Dakota by members of the Class.

w. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Loestrin 24 in Tennessee by members of the Class, in that the actions and transactions alleged herein substantially affected Tennessee with thousands of end-payors in Tennessee paying substantially higher prices for Loestrin 24 at Tennessee pharmacies.

x. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Loestrin 24 in Utah by residents of Utah who are members of the Class.

y. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Vt. Stat. Ann. 9, § 2453, *et seq.*, with respect to purchases of Loestrin 24 in Vermont by members of the Class.

z. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchases of Loestrin 24 in West Virginia by members of the Class.

aa. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Wis. Stat. § 133.01, *et seq.*, with respect to purchases of Loestrin 24 in Wisconsin by members of the Class, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of end- payors in Wisconsin paying substantially higher price for Loestrin 24 at Wisconsin pharmacies.

353. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic Loestrin 24, and (2) paying higher prices for branded Loestrin 24 than they would have paid in the absence of Defendants' conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

354. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

**THIRD CLAIM FOR RELIEF**

**Conspiracy and Combination in Restraint of Trade Under State Law (Against Warner Chilcott and Lupin)**

355. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

356. The Exclusion Payment Agreement between Warner Chilcott and Lupin involves: (a) a payment from Warner Chilcott to Lupin; and (b) an agreement by Lupin to delay marketing its generic Loestrin 24 until July 22, 2014. The payments from Warner Chilcott to Lupin under the Agreement was the quid pro quo for Lupin's agreement to delay marketing its generic versions of Loestrin 24 for over four years. Absent the payments, Lupin would not have agreed to delay marketing its generic versions of Loestrin 24 until July 22, 2014.

357. The purpose and effect of the payments flowing from Warner Chilcott to Lupin under the agreement was to delay generic competition to Loestrin 24 and there is and was no legitimate, non-pretextual, precompetitive business justification for the payment that outweighs its harmful effect. Even if there were some such conceivable justification, the payment was not necessary to achieve such a purpose.

358. The purpose and effect of the unlawful Exclusion Payment Agreement between Warner Chilcott and Lupin was to allocate 100% of the market for Loestrin 24 and its generic equivalents in the United States to Warner Chilcott; delay the sales of generic Loestrin 24 products for over four years; and fix the price at which consumers and other End-Payor Plaintiffs would pay for Loestrin 24 and its generic equivalents at the higher, branded price.

359. The Exclusion Payment Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

360. As a direct and proximate result of Defendants' unlawful restraint of trade, Plaintiffs and members of the Class paid artificially inflated prices for Loestrin 24 and its generic equivalents as described herein, and were harmed as a result.

361. By engaging in the foregoing conduct, Defendants have violated the following state laws:

a. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Arizona Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases of Loestrin 24 in Arizona by members of the Class.

b. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Cal. Bus. Code §§ 16700, *et seq.*, and Code §§ 17200, *et seq.*, with respect to purchases of Loestrin 24 in California by members of the Class.

c. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of D.C. Code Ann. §§ 28-45031, *et seq.*, with respect to purchases of Loestrin 24 in the District of Columbia by members of the Class.

d. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Fla. Stat. §§ 501. Part II, *et seq.*, with respect to purchases of Loestrin 24 in Florida by members of the Class, and this conduct constitutes a predicate act under the Florida Deceptive Practices Act.

e. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Loestrin 24 in Illinois by members of the Class.

f. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Iowa Code §§ 553.5 *et seq.*, with respect to purchases of Loestrin 24 in Iowa by members of the Class.

g. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Loestrin 24 in Kansas by members of the Class.

h. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases of Loestrin 24 in Maine by members of the Class.

i. Defendant have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Mass. Ann. Laws ch. 93, *et seq.*,

with respect to purchases of Loestrin 24 in Massachusetts by members of the Class.

j. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to purchases of Loestrin 24 in Michigan by members of the Class.

k. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Minn. Stat. §§ 325D.52, *et seq.*, with respect to purchases of Loestrin 24 Minnesota by members of the Class.

l. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases of Loestrin 24 in Mississippi by members of the Class.

m. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of Loestrin 24 in Nebraska by members of the Class.

n. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Nev. Rev. Stat. Ann. § 598A, *et seq.*, with respect to purchases of Loestrin 24 in Nevada by members of the Class, in that thousands of sales of Loestrin 24 took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct.

o. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of Loestrin 24 in New Mexico by members of the Class.

p. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of New York General Business Law § 340, *et seq.*, with respect to purchases of Loestrin 24 in New York by members of the Class.

q. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Loestrin 24 in North Carolina by members of the Class.

r. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of N.D. Cent. Code § 51-08.1-01, *et seq.*, with respect to purchases of Loestrin 24 in North Dakota by members of the Class.

s. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Loestrin 24 in Oregon by members of the Class.

t. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of 10 L.P.R.A. §§ 260, *et seq* with respect to purchases of Loestrin 24 in Puerto Rico by members of the Class.

u. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of R.I. Gen. Laws §§ 6-36-5, *et seq.* with respect to purchases of Loestrin 24 in Rhode Island by members of the Class.

v. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of S.D. Codified Laws Ann. § 37-1, *et seq.*, with respect to purchases of Loestrin 24 in South Dakota by members of the Class.

w. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Loestrin 24 in Tennessee by members of the Class, in that the actions and transactions alleged herein substantially affected Tennessee with thousands of end-payors in Tennessee paying substantially higher prices for Loestrin 24 at Tennessee pharmacies.

x. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Loestrin 24 in Utah by residents of Utah who are members of the Class.

y. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Vt. Stat. Ann. 9, § 2453, *et seq.*, with respect to purchases of Loestrin 24 in Vermont by members of the Class.

z. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchases of Loestrin 24 in West Virginia by members of the Class.

aa. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Wis. Stat. § 133.01, *et seq.*, with respect to purchases of Loestrin 24 in Wisconsin by members of the Class, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of end- payors in Wisconsin paying substantially higher price for Loestrin 24 at Wisconsin pharmacies.

362. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic Loestrin 24, and (2) paying higher prices for branded Loestrin 24 than they would have paid in the absence of Defendants' conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

363. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

## FOURTH CLAIM FOR RELIEF

**Conspiracy and Combination in Restraint of Trade**
**Under State Law**
**(Against All Defendants)**

364. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

365. By entering the Exclusion Payment Agreements, Warner Chilcott engineered an agreement with, between and among itself and the Generic Defendants not to compete with each other and to delay generic entry, which constituted a continuing illegal contract, combination and conspiracy in restraint of trade.

366. In or about January 2009 and at times before the formal execution thereof, Warner Chilcott and Watson entered into the Warner Chilcott/Watson Exclusion Payment Agreement under which Warner Chilcott agreed to make substantial payments to Watson in exchange for its agreement to delay bringing its generic version of Loestrin 24 to the market. As part of that conspiracy, Warner Chilcott agreed, among other things, that: (1) it would not license any other generic manufacturer to enter the market until 180 days after Watson entered; and (2) if any

other generic manufacturer entered the market before January 22, 2014, Watson's entry date would be accelerated accordingly.

367. During the negotiation of its Exclusion Payment Agreement with Warner Chilcott, Lupin was aware of these two terms (among others) of the Warner Chilcott/Watson conspiracy. Lupin joined that ongoing conspiracy by, among other things, agreeing not to enter before January 22, 2014, which would have triggered earlier entry by Watson, and by accepting an entry date, pursuant to the terms of the conspiracy initiated by Warner Chilcott and Watson, that was 180 days beyond the specified entry date for Watson.

368. The purpose and effect of the conspiracy was to: (1) allocate to Warner Chilcott 100% of the market for oral contraceptives consisting of 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets and its generic equivalents in the United States; (2) delay or impair the market entry of generic versions of the oral contraceptives consisting of 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets, i.e., AB-rated generic versions of Loestrin 24; and (3) fix at supracompetitive levels the price that end-payors would pay for the oral contraceptive comprised of 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets.

369. There are and were no legitimate non-pretextual, procompetitive business justifications for this unlawful conspiracy that outweigh its harmful effects.

370. As a direct and proximate result of Defendants' concerted illegal conduct, contract, combination and conspiracy in restraint of trade as alleged herein, Plaintiffs and members of the Class paid artificially inflated prices for Loestrin 24 as described herein and were harmed as a result.

371. By engaging in the foregoing conduct, Defendants have intentionally and wrongfully engaged in one or more combinations and conspiracies in restraint of trade in violation of the following state laws:

a. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Arizona Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases of Loestrin 24 in Arizona by members of the Class.

b. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Cal. Bus. Code §§ 16700, *et seq.*, and Code §§ 17200, *et seq.*, with respect to purchases of Loestrin 24 in California by members of the Class.

c. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of D.C. Code Ann. §§ 28-45031, *et seq.*, with respect to purchases of Loestrin 24 in the District of Columbia by members of the Class.

d. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Fla. Stat. §§ 501. Part II, *et seq.*, with respect to purchases of Loestrin 24 in Florida by members of the Class, and this conduct constitutes a predicate act under the Florida Deceptive Practices Act.

e. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Loestrin 24 in Illinois by members of the Class.

f. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Iowa Code §§ 553.5 *et seq.*, with respect to purchases of Loestrin 24 in Iowa by members of the Class.

g. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Loestrin 24 in Kansas by members of the Class.

h. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases of Loestrin 24 in Maine by members of the Class.

i. Defendant have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Mass. Ann. Laws ch. 93, *et seq.*, with respect to purchases of Loestrin 24 in Massachusetts by members of the Class.

j. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to purchases of Loestrin 24 in Michigan by members of the Class.

k. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Minn. Stat. §§ 325D.52, *et seq.*, with respect to purchases of Loestrin 24 Minnesota by members of the Class.

l. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases of Loestrin 24 in Mississippi by members of the Class.

m. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of Loestrin 24 in Nebraska by members of the Class.

n. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Nev. Rev. Stat. Ann. § 598A, *et seq.*, with respect to purchases of Loestrin 24 in Nevada by members of the Class, in that thousands of sales of Loestrin 24 took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct.

o. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of Loestrin 24 in New Mexico by members of the Class.

p. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of New York General Business Law § 340, *et seq.*, with respect to purchases of Loestrin 24 in New York by members of the Class.

q. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Loestrin 24 in North Carolina by members of the Class.

r. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of N.D. Cent. Code § 51-08.1-01, *et seq.*, with respect to purchases of Loestrin 24 in North Dakota by members of the Class.

s. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Loestrin 24 in Oregon by members of the Class.

t. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of 10 L.P.R.A. §§ 260, *et seq* with respect to purchases of Loestrin 24 in Puerto Rico by members of the Class.

u. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of R.I. Gen. Laws §§ 6-36-5, *et seq.* with respect to purchases of Loestrin 24 in Rhode Island by members of the Class.

v. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of S.D. Codified Laws Ann. § 37-1, *et seq.*, with respect to purchases of Loestrin 24 in South Dakota by members of the Class.

w. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Loestrin 24 in Tennessee by members of the Class, in that the actions and transactions alleged herein substantially affected Tennessee with thousands of end-payors in Tennessee paying substantially higher prices for Loestrin 24 at Tennessee pharmacies.

x. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Loestrin 24 in Utah by residents of Utah who are members of the Class.

y. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Vt. Stat. Ann. 9, § 2453, *et seq.*, with respect to purchases of Loestrin 24 in Vermont by members of the Class.

z. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchases of Loestrin 24 in West Virginia by members of the Class.

aa. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Wis. Stat. § 133.01, *et seq.*, with respect to purchases of Loestrin 24 in Wisconsin by members of the Class, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of end- payors in Wisconsin paying substantially higher price for Loestrin 24 at Wisconsin pharmacies.

372. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist

of: (1) being denied the opportunity to purchase lower-priced generic oral contraceptives consisting of 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets, and (2) paying higher prices for oral contraceptives consisting of 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets than they would have paid in the absence of Defendants' conduct. These injuries are of the type the laws of the above States, the District of Columbia, and Puerto Rico were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

373. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

## FIFTH CLAIM FOR RELIEF

**For Unfair or Unconscionable Acts and Practices**
**Under State Law**
**(Against All Defendants)**

374. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

375. Defendants engaged in unfair competition or unfair or unconscionable acts or practices in violation of the state consumer protection statutes listed below.

376. There was a gross disparity between the price that Plaintiffs and the End-Payor Class members paid for the brand product and the value received, given that a less expensive substitute generic product should have been available.

377. As a direct and proximate result of Defendants' unfair competition or unfair or unconscionable acts or practices in violation of the state consumer protection statutes listed below, Plaintiffs and End-Payor Class members were deprived of the opportunity to purchase a generic version of Loestrin 24 and forced to pay higher brand prices.

378. By engaging in the foregoing conduct, Defendants have violated the following state unfair trade practices and consumer fraud laws:

a. Defendants have engaged in unfair competition or unfair acts or practices in violation of Ariz. Rev. Stat. §§ 44-1522, *et seq.*

b. Defendants have engaged in unfair competition or unfair acts or practices in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.*

c. Defendants have engaged in unfair competition or unfair acts or practices or made false representations in violation of D.C. Code §§ 28-3901, *et seq.*

d. Defendants have engaged in unfair competition or unfair acts or practices in violation of Fla. Stat. §§ 501.201, *et seq.*

e. Defendants have engaged in unfair competition or unfair acts or practices in violation of Haw. Rev. Stat. §§ 480, *et seq.*

f. Defendants have engaged in unfair competition or unfair acts or practices in violation of Iowa Code §§ 714.16, *et seq.*

g. Defendants have engaged in unfair competition or unfair acts or practices in violation of Idaho Code Ann. §§ 48-601, *et seq.*

h. Defendants have engaged in unfair competition or unfair acts or practices in violation of 815 Ill. Comp. Stat. Ann. §§ 505/1, *et seq.*

i. Defendants have engaged in unfair competition or unfair acts or practices in violation of Kan. Stat. Ann. §§ 50-623, *et seq.*

j. Defendants have engaged in unfair competition or unfair acts or practices in violation of Me. Rev. Stat. tit. 5 §§ 207, *et seq.*

k. Defendants have engaged in unfair competition or unfair acts or practices in violation of Mass. Gen. Laws ch. 93A, *et seq.*

l. Defendants have engaged in unfair competition or unfair acts or practices in violation of Mich. Comp. Laws Ann. §§ 445.901, *et seq.*

m. Defendants have engaged in unfair competition or unfair acts or practices in violation of Mo. Ann. Stat. §§ 407.010, *et seq.*

n. Defendants have engaged in unfair competition or unfair acts or practices in violation of Mont. Code Ann. §§ 30-14-101, *et seq.*

o. Defendants have engaged in unfair competition or unfair acts or practices in violation of Neb. Rev. Stat. §§ 59-1601, *et seq.*

p. Defendants have engaged in unfair competition or unfair acts or practices in violation of Nev. Rev. Stat. §§ 598.0903, *et seq.*

q. Defendants have engaged in unfair competition or unfair acts or practices in violation of N.H. Rev. Stat. Ann. §§ 358-A:1, *et seq.*

r. Defendants have engaged in unfair competition or unfair acts or practices in violation of N.M. Stat. Ann. §§ 57-12-1, *et seq.*

s. Defendants have engaged in unfair competition or unfair acts or practices in violation of N.Y. Gen. Bus. Law §§ 349, *et seq.*

t. Defendants have engaged in unfair competition or unfair acts or practices in violation of N.C. Gen. Stat. §§ 75-1.1, *et seq.*

u. Defendants have engaged in unfair competition or unfair acts or practices in violation of R.I. Gen. Laws §§ 6-13.1-1, *et seq.*

v. Defendants have engaged in unfair competition or unfair acts or practices in violation of Tenn. Code Ann. §§ 47-18-101, *et seq.*

w. Defendants have engaged in unfair competition or unfair acts or practices in violation of Utah Code Ann. §§ 13-11-1, *et seq.*

x. Defendants have engaged in unfair competition or unfair acts or practices in violation of Vt. Stat. Ann. tit. 9 §§ 2451, *et seq.*

y. Defendants have engaged in unfair competition or unfair acts or practices in violation of W. Va. Code §§ 46A-6-101, *et seq.*

379. Plaintiffs and members of the Class have been injured in their business and property by reason of Defendants' anticompetitive, unfair acts alleged in this Claim. Their injury consists of paying higher prices for Loestrin 24 than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

## SIXTH CLAIM FOR RELIEF

**Unjust Enrichment**

**(Against All Defendants)**

380. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

381. Defendants have benefited from splitting the monopoly profits on Warner Chilcott's Loestrin 24 sales resulting from the unlawful and inequitable acts alleged in this Complaint.

382. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for Loestrin 24 and Minastrin 24 by Plaintiffs and members of the Class.

383. Plaintiffs and the Class have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiffs and the Class.

384. It would be futile for Plaintiffs and the Class to seek a remedy from any party with whom they had privity of contract. Defendants have paid no consideration to anyone for any benefits received indirectly from Plaintiffs and the Class.

385. It would be futile for Plaintiffs and the Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which it indirectly purchased Loestrin 24, as they are not liable and would not compensate Plaintiffs for unlawful conduct caused by Defendants.

386. The economic benefit of overcharges and unlawful monopoly profits derived by Defendants through charging supracompetitive and artificially inflated prices for Loestrin 24 is a direct and proximate result of Defendants' unlawful practices.

387. The financial benefits derived by Defendants rightfully belongs to Plaintiffs and the Class, as Plaintiffs and the Class paid anticompetitive and monopolistic prices during the Class Period, inuring to the benefit of Defendants.

388. It would be inequitable under the laws of all states and jurisdictions within the United States, except for Indiana and Ohio, for the Defendants to be permitted to retain any of the overcharges for Loestrin 24 derived from Defendants' unfair and unconscionable methods, acts and trade practices alleged in this Complaint.

389. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiffs and the Class all unlawful or inequitable proceeds received by them.

390. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiffs and the Class.

391. Plaintiffs and the Class have no adequate remedy at law.

## SEVENTH CLAIM FOR RELIEF
### Declaratory and Injunctive Relief
### (Against Warner Chilcott)

392. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

393. As described above, at all relevant times, Warner Chilcott possessed monopoly power in the relevant market—i.e. the market for oral contraceptives consisting of 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets in the United States. But for Defendants' wrongful conduct, Defendants would have lost their monopoly power in the relevant market on or about September 2009.

394. As stated more fully above, Defendants knowingly, willfully, and wrongfully maintained their monopoly power.

395. Plaintiffs and the Class, pursuant to Fed. R. Civ. P. 57 and 18 U.S.C. § 2201(a) hereby seek a declaratory judgment that Defendants' conduct in seeking to prevent competition as described in this action comprises illegal monopolization in violation of Section 2 of the Sherman Act.

396. Plaintiffs and the Class further seek permanent equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, against threatened loss or damage resulting from Defendants' violations of the antitrust laws, and other relief so as to assure that similar anticompetitive conduct does not reoccur in the future.

397. As a remedy to prevent further harm, Plaintiffs and the Class seek an injunction requiring the Defendants to grant a compulsory, royalty-free license for Minastrin 24 to any entity who is approved by the FDA to market pharmaceuticals in the United States.

## XIII. DEMAND FOR JUDGMENT

398. WHEREFORE, Plaintiffs, on behalf of themselves and the End-Payor Class, demands judgment for the following relief:

a. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a), 23 (b)(2) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class and declare the Plaintiffs representative of the End-Payor Class;

b. Declare that the conduct alleged herein is in violation of Section 1 of the Sherman Act, of the other statutes set forth above, and of the common law of unjust enrichment under the laws of all states and jurisdictions within the United States;

c. Declare that the conduct alleged herein is in violation of Section 2 of the Sherman Act, and enter an injunction pursuant to Section 16 of the Clayton Act requiring the Defendants to grant a compulsory license for Minastrin 24 to any entity who is approved by the FDA to market pharmaceuticals in the United States;

d. Enter joint and several judgments against Defendants in favor of Plaintiffs and the End-Payor Class;

e. Grant Plaintiffs and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a construction trust to remedy Defendants' unjust enrichment;

f. Award the End-Payor Class damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;

g. Award Plaintiffs and the End-Payor Class their costs of suit, including reasonable attorneys' fees as provided by law; and

h. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and as the Court deems just.

## XIV. JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs on behalf of themselves and the proposed Class demand a trial by jury on all issues so triable.

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***End Payors' Interim Executive Committee***

**CERTIFICATE OF SERVICE**

I, Marvin A. Miller, hereby certify that I caused a copy of the redacted public version of End Payor Plaintiffs' Second Amended Consolidated Class Action Complaint to be filed electronically via the Court's CM/ECF system. Those attorneys who are registered CM/ECF users may access these filings, and notice of these filings will be sent to those parties by operation of the CM/ECF system.

Dated: May 9, 2016

/s/ Marvin A. Miller
Marvin A. Miller